IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

RETRACTABLE TECHNOLOGIES INC.	*	Civil Docket No.
	*	2:07-CV-250
VS.	*	Marshall, Texas
	*	November 2, 2009
BECTON DICKINSON & COMPANY	*	8:45 A.M.

TRANSCRIPT OF JURY TRIAL
BEFORE THE HONORABLE DAVID FOLSOM
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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(Proceedings recorded by mechanical stenography, transcript produced on CAT system.)

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P R O C E E D I N G S

(Jury out.)

COURT SECURITY OFFICER: All rise.

THE COURT: As a matter of fact of housekeeping, I believe the Court was notified by e-mail, but it's not part of the record, that the Plaintiff wishes to dismiss its DOE claim, is that correct, of infringement?

MR. HARDIN: That is correct, Your Honor.

THE COURT: And the Defendants wish to --

or Defendant -- dismiss certain invalidity claims; is that correct?

MR. BECK: That is correct, Your Honor.

THE COURT: And what are those, for purpose of the record, or can we have some written stipulation later in the day?

MR. BECK: We will, Your Honor, a written stipulation later.

MR. HARDIN: That's fine, Your Honor.

THE COURT: Very well.

I considered the motion concerning the limiting instruction that's part of the record as a result of Mr. Beck's statement during opening. And I'm of the opinion, since the DOE claim was still in at the time, that that was not a violation of the Court's limine order and will deny the requested instruction.

Any other matters?

It's my understanding Plaintiff wishes to use a little short time --

MR. CARROLL: That's correct, Your Honor.

THE COURT: Then the Defendant will let us know, after you hear it, whether you want to respond.

MR. BECK: That is correct.

THE COURT: Very well. Let's bring the jury in, and then we'll start today's testimony.

(Jury in.)

THE COURT: Please be seated, Ladies and Gentlemen.

Good morning. I hope everyone had a pleasant weekend.

Very shortly, we will start testimony in the trial, but I've given each side of the case up to 30 minutes during the course of the trial to make what we call interim statement, with no more than five minutes being used at any one time.

And the Plaintiff wishes to exercise up to five minutes of that time. And if the Defendant wishes to respond, they're entitled to do so up to five minutes.

Mr. Carroll.

MR. CARROLL: Thank you, Your Honor. If the Court please.

Good morning.

THE JURY: Good morning.

MR. CARROLL: You have with you your jury notebook. This is kind of like for a football player, your playbook. And I want to talk to you just a little bit this morning --

THE COURT: Mr. Carroll, do I have a copy, or do you have an extra copy for me?

MR. CARROLL: You can sure have mine, Judge.

Do we have an extra one?

THE COURT: I have one right here.

MR. CARROLL: Okay.

THE COURT: I will take my clerk's, so if you have an extra copy for them.

MR. CARROLL: I will give them mine, Judge. If I can remember what page I'm on.

LAW CLERK: You can have it.

MR. CARROLL: Can I give it to you afterwards? Thank you.

So in my opinion, the significance of this notebook is that it will give you a way to keep up today, and every day, in two regards.

First of all, you'll look that the patents are in the -- in the notebook. The patents -- remember, we have patents that are at issue in this case issued by the government, and we claim they are infringing or trespassing on our patents.

The patents are in here, and that's the first three tabs.

The fourth tab is a very, very important tab. The fourth tab -- and if everybody would turn to that and look up at the top -- everybody on the fourth tab?

Look up at the top, and you'll see the word -- there's a chart there -- Tab 4. Okay. And you'll see up at the left hand -- up at the top on the left hand, it says term. Then on the right hand, it says Court's construction.

Remember, Judge Folsom told you there were two judges: The fact judges, which are you-all, and law judges, which is His Honor. That's part of the law judge's job, is to tell us where our fence line is for this patent.

Remember, I told you a patent is like a deed, and we're entitled to keep out anybody, without permission, out of our fence line.

Judge Folsom tells you where the fence line is. That's why this is important, and this is not for me to decide or for Mr. Beck to decide or for you-all to decide; the Judge has done that.

So let me tell you what you're going to hear this morning from us, from RTI, the Plaintiff.

We're the one asking for help on this infringement case.

Flip over to Page 5 -- I'm sorry -- Tab 5, and there's a picture or page with some pictures. Look on the second -- on the left-hand column in the middle picture. That's Ms. Duesman. And she's not too pleased with her picture, but I think it's a good one.

And here's -- Ms. Duesman will be our first witness. And I may have told you a little bit about this on Friday, but Ms. Duesman is a registered nurse who has been a registered nurse for 24 years.

I told her this morning, I said you've done it almost a quarter of a century. She said that sounds way old, way long. I said, okay, how about 24 years? So she's done that 24 years.

And let me tell you what she's going to tell you. She's going to tell you why Mr. Shaw's invention did what the patent law calls satisfied a long-felt need. That's a patent term. But what it means is, it solved a problem that was a big problem and an unsolved problem.

And she's going to tell you about that from the standpoint of somebody, who has, for a long time, took care of patients. And she's going to tell you how she learned about the Shaw technology and why it caused her not only to join the company as an employee, but how it caused her and her former rancher husband to invest in the company.

She -- they really put their mouth--- their money where their mouths were. So that's what you're going to hear from Ms. Duesman. She will be the first witness.

The second witness is -- let me find my tab here -- the second witness is right under Ms. Duesman's picture, Neil Sheehan.

THE COURT: Mr. Carroll, I am told your five minutes has been used. I will give you an additional 30 seconds since we used part of your time trying to locate my copy of --

MR. CARROLL: Okay.

THE COURT: So if you'll round up your comments in the next 30 seconds.

MR. CARROLL: Okay. Neil Sheehan is going to talk about infringement. Let me tell you what he's going to say, and this is very important.

He is going to refer you back to Judge Folsom's description of our property line, and he's going to tell you that what's important is not what releases that needle, whether it's cut or torn or anything else, that that's not what Judge Folsom tells you is important.

And you'll find that in the book.

What's important is what holds it, what holds that spring and holds that needle. And if it's friction, Judge Folsom says, or if it's clamping, Judge

Folsom says that's in our fence line.

And if you find, based on what you hear from Mr. Sheehan, that they either hold by clamping or friction, regardless of what cuts it loose, whether it's cutting or tearing or anything else, we win.

Thank you.

THE COURT: Response on behalf of Defendant?

MS. PIROZZOLO: No response, but may we approach the bench, Your Honor?

THE COURT: Yeah.

(Bench conference.)

THE COURT: Now, are you taking the witness on cross-examination?

MS. PIROZZOLO: No, Your Honor.

THE COURT: Okay.

MS. PIROZZOLO: Mr. Carroll indicated that Ms. Duesman is going to discuss long-felt need, and I think we need some guidance from the Court, because she wasn't disclosed as an expert in this case.

And in addition, the invention here is a particular type of retraction mechanism, and any solution to needlestick injuries is not -- is no nexus.

THE COURT: I think she can -- as far as going to the expert witness, I don't think she has to be designated as an expert witness just on general background information, the use of the needle.

MR. CARROLL: That's all we're going to do.

THE COURT: What's your reply to the second --

MR. CARROLL: I guess I didn't understand it. I'm sorry.

MS. PIROZZOLO: Okay. The invention here is a particular type of retraction mechanism, not any -- any solution to needlestick injuries. So saying that the long-felt need was any type of solution to needlestick injuries, there's no nexus between the claims being asserted against Becton Dickinson, which are a particular type of retraction mechanism and needlestick injuries in general.

MR. CARROLL: Okay. Judge, here was my point, and that is, we're going to put her up there to talk about how she found out about this, how she joined the company, what the company is, what they do, and then why -- you know, why she joined us, because she saw a thing on the television, and she thought it was great.

THE COURT: Well, obviously raise an objection if he tries to go outside.

MR. CARROLL: And I'm not trying to dance around it. I just -- frankly, I don't understand it, but it's my problem, not your problem.

MS. PIROZZOLO: Nexus.

THE COURT: Obviously don't try to make an expert out of her.

MR. CARROLL: Oh, Judge, I'm not. That's the last thing we need is another expert.

(Bench conference concluded.)

MR. CARROLL: May I proceed?

THE COURT: Yes, you may.

MR. CARROLL: Your Honor, I don't believe Ms. Duesman has been sworn.

THE COURT: Come around, please.

Has the Rule been requested?

MR. BECK: It has, Your Honor.

THE COURT: Very well.

Are there any witnesses, other than corporate representatives, individual parties? And I do allow experts to remain in the courtroom from both parties, because they, in part, can arrive at their opinion from what they hear and see in the courtroom.

So is anyone subject to the Rule that's in the courtroom?

MR. CARROLL: Not from the Plaintiff, Your Honor.

THE COURT: If the parties will help me police this.

MR. BECK: I don't see anybody from our side either, Your Honor.

THE COURT: Very well. Thank you.

COURTROOM DEPUTY: Would you raise your right hand.

(Witness sworn.)

MR. CARROLL: If the Court, please, Your Honor.

THE COURT: Yes.

KATHRYN DUESMAN, PLAINTIFF'S WITNESS, SWORN

DIRECT EXAMINATION

BY MR. CARROLL:

Q. Ms. Duesman, good morning.
A. Good morning.
Q. Would you tell the jury and the Judge and the court reporter, please, your full name and spell it for them.
A. Certainly. My name is Kathryn Duesman. Kathryn with a K, K-A-T-H-R-Y-N, Duesman, D-U-E-S-M-A-N.
Q. And where do you live?
A. I live in Pilot Point, Texas.
Q. Which is where?
A. Just north of Denton.

Q. Denton County?

A. It's actually going through the City of Denton, and it's in the northeastern corner of Denton County.

Q. Okay. So we've heard a little bit Friday -- excuse me -- and a little bit this morning about that area and RTI being in a little place called Little Elm.

MR. CARROLL: Would you tell me how to turn on my machine, or is it on?

Q. (By Mr. Carroll) Okay. Look up here at the map, Ms. Duesman.

And there's a dot above Lewisville called Little Elm. What's the significance of Little Elm, Texas, to this lawsuit?

A. That's where the manufacturing facility is and the headquarters of Retractable Technologies.

Q. That's -- that's all of us over here at this table?

A. Yes, it is.

Q. Now you told the jury a second ago that you live in a place called Pilot Point. Where is it?

A. It's just north of Little Elm. It's a smaller town.

Q. Okay. And that's where you are?

A. Yes, sir?

Q. Is that about right?
A. Yes.
Q. Okay. Do you actually live in the city Of Pilot Point?
A. Actually, I live right outside the city limits.
Q. I told the jury earlier that you and your husband have a farm and a ranch out there?
A. Yes.
Q. Is that how you-all earn your keep, so to speak?
A. Yes. Yes, it is.
Q. Okay. How long have you and your family lived up in the Pilot Point area?
A. I've lived there most of my life, and my husband and I have been married for 27 years. So we've been there all that time.
Q. Got children?
A. Yes, I do.
Q. Are they grown?
A. I hope so. They're --
Q. Let me ask it this way: Like Mr. Beck and I talked about, were they at home this morning?
A. No. They're --
Q. Then they are grown as of today?

A. I hope.

Q. Okay. Okay. I told the jury a minute ago that you are a 24-year experienced registered nurse. Is that true?

A. Yes.

Q. Tell the jury a little bit about how you got into that profession.

A. Well, I went to college at Texas Women's University in Denton and became a nurse. Went right to work at the county hospital in Denton, and that's where -- that's where I worked. That's where I started out working as a nurse in the obstetrical department.

Q. And you were involved, obviously, in patient care?

A. Oh, yes. I took care of patients.

Q. Now, Ms. Duesman, the jury heard a little bit on Friday about syringes and needles. Of course, that's a lot of what the case is about.

A. Yes.

Q. True?

A. Yes.

Q. And I know this sounds kind of dumb, but I assume you've given shots in your career.

A. Oh, yes, I have.

Q. And I'm assuming that when you were at nursing university in Denton, you were trained about such.

A. Yes, I was.

Q. And the jury heard on Friday that one of the issues that we're talking about in this case is how in the world do you protect folks like you from contact with contaminated needles.

You heard that?

A. Yes, I did.

Q. And you heard that we talked about a term called needlestick injury.

A. Yes.

Q. When did you first hear that?

A. I first heard of that when I was in college and certainly as a nurse working in a hospital, giving shots.

Q. Okay. What did -- what did the folks there at Texas Women's teach you in the early '80s about needlestick injury and how to protect against them?

MS. PIROZZOLO: Objection, Your Honor.

THE COURT: Excuse me?

MS. PIROZZOLO: Objection.

THE COURT: What's the basis of the objection?

MS. PIROZZOLO: Hearsay.

THE COURT: Overruled.

Q. (By Mr. Carroll) Go ahead.

A. They just taught us to be careful and to not touch the needle. We would often recap needles to cover them up, which was really kind of dangerous in and of itself.

Q. Okay. I was going to borrow Mr. Beck's giant needle, but I don't see it here today.

Did you bring some props, some needles for us to look at?

A. Yes, sir. They're not as big as his, but...

Q. Okay. I am going to walk up here toward you, with the Court's permission, or maybe I will get Mr. Potts to help me out here.

Would you please, Ms. Duesman, find in that box a sterile capped syringe and needle?

A. Yes, sir.

Q. Okay. And with the Court's permission --

MR. CARROLL: Your Honor, may she get up and walk a little bit so the jury can see that? I was hoping I could use Mr. Beck's big needle.

THE COURT: Yes, sir.

MR. CARROLL: Thank you, Your Honor.

Q. (By Mr. Carroll) All right. Just stop right there, if you would.

A. (Complies.)

Q. Now, obviously the cap -- I think everybody on the jury can see it.

A. Right there (indicates).

Q. And go ahead and take it off there, if you would?

A. (Complies.)

Q. Now, that -- that needle is supposed to be sterile, correct?

A. Yes.

Q. Now, I talked to the jury panel, before they were lucky enough to get picked on Friday, about a term that's called keeping your hand behind the sharp.

Have you ever heard that before?

A. Yes, I have.

Q. What does that mean?

A. That means you don't want to get any closer to that needle with your hand as possible. So you want to keep your hands back behind.

Q. Okay. And you mentioned to the jury a second ago that you were taught that recapping a contaminated needle is bad business, correct?

A. Yes.

Q. Why?

A. It's very dangerous. If you bring that cap forward, you have a really good chance of sticking yourself with that dirty needle. And if you do, you can get sick.

Q. Okay. Now, Ms. Duesman -- thank you. You can return to your seat, with the Court's permission.

A. (Complies.)

Q. Now, Ms. Duesman, what did you do after you got licensed?

I think you told the jury you worked in a hospital up there in Denton County, maybe helping them deliver babies?

A. Yes, sir.

Q. At that point in the practice, the nursing practice, was there any -- to your remembrance, was there any kind of, quote, safe needle?

A. No.

Q. How did you all protect yourself as nurses back in the '80s?

A. When I first started working at the county hospital, we would give an injection in the patient's room and usually recap the dirty needle and take it back to the nurses' station.

And at that hospital, we usually had a needle cutter, and we would actually cut the needles off, and it was -- that was a long time ago.

Q. Not so long --

A. Well --
Q. -- to some of us.
A. And that's where you would dispose of it. But that's -- that's what I did when I was right out of school in '85.
Q. And that was -- was that the standard at that time?
MS. PIROZZOLO: Objection, Your Honor.
MR. CARROLL: I withdraw that question.
Q. (By Mr. Carroll) That's how you were taught?
A. I should say that's how that hospital handled their contaminated sharps.
Q. Okay. Now, what is a sharp box?
MR. CARROLL: By the way, do we have one?
Q. (By Mr. Carroll) Okay. Is this a sharp box?
A. Yes, it is.
Q. And I guess the purpose of this is pretty obvious when you look at what's inside, right?
A. Yes.
Q. What's the purpose of a sharp box?
A. It's a puncture-resistant container to put contaminated sharps in until after you've used them.
Q. Okay. Now, Ms. Duesman, I want to take you forward a little bit from 1985, when you got your license and hired on up there at the hospital in

Denton -- excuse me.

When did you first hear or learn about so-called retractable needles?

A. The first time I ever saw the retractable technology was on a local news story that was talking about the fact that they were going to build a syringe factory in Little Elm, which wasn't very far from my home.

And I didn't even hear the name of the company, but when I happened to look at the TV, I saw a closeup of that technology and saw the needle disappear, and I kind of wished they would do it again, because it was really -- really pretty interesting and amazing to me.

Q. And what happened after that?

A. Well, after that, I told my husband about it, that they're building a syringe factory in Little Elm, Texas. And he happened to be looking in the paper, the local paper, and they had an ad looking for nurses to come work for a company and train people on a new technology.

Q. Now, wait a minute. I thought you had a job.

A. I did. I was working at the hospital nights. By then, I had several little kids, so I worked during the nighttime.

Q. Okay. Looking for a day job?
A. Always looking for a day job.
Q. So what happened?
A. Again, I didn't even know the name of the company, but I was so interested in the technology, I called the phone number and went down there to apply for a job.
Q. And when you say you went down there, look up here on the screen. Is this where you went?
A. That's where I went.
Q. Tell the jury a little bit about what that building looked like back -- what year would this have been, by the way?
A. That would have been in 1996.
Q. Thirteen years ago?
A. Yes, sir.
Q. And you drove, I guess -- where is this little building or was it?
A. That little building is in Lewisville, Texas.
Q. Okay. And back to our little map, that's just south of where you-all were, right?
A. Correct.
Q. Okay. And tell the jury a little bit about what you -- by the way, did you go by yourself?
A. Yes.

Q. What did you find when you got there?
A. That little building, which honestly wasn't very impressive. But I went in and filled out an application, and they -- they showed me the syringe, and, sure enough, it was the same one I had seen on TV and --
Q. What was your reaction when you saw it?
A. I thought it was the safest way to give a shot.
Q. Had you ever seen anything like it?
A. Never.
Q. Did you ask any questions about it?
A. Sure. Sure, I did.
Q. Like what?
A. The -- one of the first things I asked -- I knew it was safe for giving a shot, but I asked how patients felt about it, how did it feel to them.
Q. Did you get any reply from them without getting into any detail about who said what?
A. No. They -- that said that patients reacted well.
Q. Okay. Did you believe that?
A. I wanted to know for sure.
Q. How did you -- how did you test it out?
A. I asked if I could have a syringe to take with

me, and they told me I couldn't. But I came back for another interview, and I guess I probably signed some papers by then, and I -- they let me have a sterile syringe.

And I still had my night job. I still wasn't sure about all this, so I actually had a little vile of sterile saline that I had, and I drew up some and I made my husband let me give him a shot and --

Q. So he was the guinea pig?

A. Yes, he was.

Q. Well, did he live?

A. He lived.

Q. As a matter of fact, I think he's in the courtroom. There he is right there (indicates).

A. Yes.

Q. Stand up and let's make sure you're still alive.

Okay. He doesn't look too much worse for the wear.

A. No, he did fine.

Q. Okay. Did you have any other concerns?

A. I asked if they -- if they had patented this technology.

Q. What did you learn?

A. They said they had.

Q. Okay. Now, Ms. Duesman, that was way back in 198 -- I mean '96.

Did you hire on with them?

A. Yes, I did.

Q. Doing what?

A. Training nurses on the technology, training them how to use it and how it worked.

Q. Are you still in that same job today?

A. Yes, I am. That's what I do. Not to maybe people in different places, but that's what I'm still doing.

Q. As a matter of fact, you've got global duties today, do you not?

A. Yes, I do.

Q. I mean, like traveling overseas and whatnot?

A. Yes. But the trips are longer, but what I do is pretty much the same.

Q. A long way from Pilot Point?

A. Yes. Yes, it is.

Q. All right. Let me show you another picture. And what's this?

A. That's the manufacturing facility where they make our syringes, our technology.

Q. Now, that is in Little Elm, right?

A. Yes, sir.

Q. How many folks work for our company?
A. About -- about 150.
Q. They're at Little Elm?
A. Yes.
Q. Is that where you go to work every day?
A. Actually, now I -- because I travel quite a bit, I work from my home, and I go in frequently for meetings and anything they need me for at the plant, at the factory.
Q. Excuse me. Of course, we got a lawsuit against our friends over here at B&D.
You know who they are?
A. Yes, I do.
Q. As I understand from Mr. Beck on Friday, they're just three or four counties away in Bowie County in Texarkana, correct?
A. No, I don't think so.
Q. Do they have a manufacturing facility in Bowie County?
A. Not that I'm aware of.
Q. Do they have any employees that you know of in Bowie County?
MS. PIROZZOLO: Judge?
THE COURT: Mr. Carroll?
MR. CARROLL: I was just trying to find

out a little bit about the opponent, Your Honor.

THE COURT: Well, if she knows, I will allow her to answer. Overruled.

Q. (By Mr. Carroll) Do you know anything about whether they, in fact, have any presence in the state of Texas?

A. I don't know of any factories or anything like that.

Q. Where are they?

MS. PIROZZOLO: Objection, Your Honor.

Q. (By Mr. Carroll) If you know.

A. Well, I know the headquarters are --

THE COURT: I'll overrule. I'll allow her if show knows where the headquarters is located.

MR. CARROLL: Thank you, Your Honor.

Q. (By Mr. Carroll) Where do you know their headquarters to be?

A. In New Jersey.

Q. Where is your headquarters?

A. In Little Elm, Texas.

Q. Okay. Based on your experience as a registered nurse, was there a point in your career where the federal government got involved in needlestick injuries?

A. Yes.

In 1991, they -- the federal government, OSHA, the Occupational Safety and Health Administration, issued regulations.

Q. Let me stop you right there.

How do you know that?

A. I -- I know it because it changed the way we did things in hospitals.

Q. You as a -- as a patient-care nurse at that point?

A. Yes, sir.

Q. Okay. And did -- did you learn that on the job, so to speak, that the rules had changed?

A. Well, actually, the regulation was issued in 1991. I actually was home. I had just had a baby, so I had quit work for a little while, and I came back in '92.

And just the way you handled contaminated sharps was a lot different, and there were different policies that you needed to do at the hospital.

Q. Did OSHA change the way you dealt with these boxes?

A. Yes.

Q. How so?

A. No more cutting needles. That was gone. And you weren't to be recapping any needles, ever. And they actually -- part of the -- part of the regulations were that those sharps boxes were at the point of use. So you didn't have to use them and walk down the hall to put them away. They would be right there at the patient's bedside, for example.

Q. Okay. Ms. Duesman, I've written on my chalkboard here the phrase, minimize or eliminate, and then I put in red, exposure to contaminated needles.

A. Yes.

Q. Is this -- is this the first time you've heard that phrase?

A. Oh, no. That -- that is in the OSHA regulations. Actually, I think what it says is you must minimize or eliminate the exposure to contaminated sharps --

Q. Okay.

A. -- which is the same as needles.

Q. I'm going to get it right, so I'm going to scratch out needle and write in sharps.

I have written in the term, exposure. Why are they talking about exposure?

A. My understanding of the regulations is they don't -- they don't want healthcare workers to even be exposed to the contaminated sharp or to minimize, at the bare minimum, any exposure to prevent a needlestick injury.

Q. That was back in '91?

A. Yes.

Q. Did the government get into the business of telling manufacturers, such as B&D and RTI, how to make a safer needle?

A. No.

Q. After 1991, you, as a practicing registered nurse before '96 when you saw Mr. Shaw's technology, did you see any attempts out in hospitals and doctors' offices and whatever by industry to comply with eliminating the exposure to contaminated sharps?

A. Well, I -- I did see the change in the location of sharps boxes. I did see some changes in some of the IV systems. I didn't see any different syringes at that time.

Q. Okay. Did you ever hear of a law that was passed in 2000 called the Needlestick Prevention Act?

A. Yes.

Q. What was that all about, from your experience as a registered nurse?

A. That was a law -- my understanding of the law that was passed that really made an emphasis on new technologies to eliminate that, to eliminate the exposure that we talked about. And it broadened up the regulations. It made them a little bit more specific. It also had different components in that. And it was -- actually, that law revised those OSHA regulations. So they issued those OSHA regulations in 2001 right after the law to -- to reflect that they broadened what the terms meant. They made it a little more specific.

Q. For instance, did the government specify that it was a no-no to recap a dirty needle?

A. Yes. Yes.

Q. For the reasons that you just told the jury?

A. Yes, sir.

Q. Now, Ms. Duesman, comes the fun part. I want you -- with the Court's permission, I want you to give me a shot. Not a real shot.

Do you have your --

A. Yes, I do.

Q. -- pad?

MR. CARROLL: Your Honor, may she come down and I join her over here on the side?

By the way, I'd be glad for anybody here to take a shot.

MR. BECK: Is it a real shot?

Q. (By Mr. Carroll) Okay. Now, here is what I would ask you to do, Ms. Duesman, with Judge Folsom's permission: I want you to show the jury what we have here.

Got a pad, right? That's the one I used on Friday.

What else do we have?

A. Well, I have a standard syringe and the retractable.

Q. Okay. When you say standard syringe, what do you mean by standard?

A. This syringe doesn't have any safety feature.

Q. Okay. So once we uncap this one and give a shot and make it contaminated, then there's no protection, so to speak?

A. Yes.

Q. Okay. And then what's this over here?

A. This is the VanishPoint syringe.

Q. Mr. Shaw's technology over here?

A. Yes.

Q. Okay. Okay. So let's -- lead us the way.

Show me how -- I get a shot. And I'll tell you I haven't had one in a while.

A. Okay.

Q. So I'm not too pleased about this. Okay.

A. Okay.

Q. I'm going to -- I'm going to move over here so the jury can see.

Tell the jury what you're doing to start with.
A. Okay. If I was giving an injection, of course, first I'd wipe the site with alcohol.
You're making it hard for me to --
Q. Well, tell me what I can do to make it easier.
A. Then I would take my syringe, which I probably would have already filled up with medication.
Q. Okay.
A. I'd give my injection and push the medication in.
Q. By the way, it didn't hurt at all.
A. And then I'd pull the needle out, and then I would hold the site, because people bleed a little bit after that.
Q. Well, what are you going to do with that dirty needle?
A. Well, I am kind of in a fix now, because the sharps box is far away, so I -- I would have to set it down probably.
Q. Now, that's not a good idea.
A. No, it's not.
Q. What about me?
A. Well, I need to put a Band-Aid on you.
Q. Okay.
A. So I need to take care of that, and then I

would have to get to a point where I could put this into a sharps container.

Q. Okay. But it's dangerous right now.

A. Well, yes, at this point, it's contaminated.

Q. Okay. All right. So that was the old way?

A. Yes.

Q. All right. Why don't you recap that baby, even though we're not supposed to do that.

By the way, is it a good idea to reuse needles?

A. No.

Q. I mean, that's kind of a dumb question. I think everybody knows that.

What about reusing the actual syringe?

A. No. That would be dangerous.

Q. Show the jury the difference between the needle and the syringe while we're standing here.

A. This is the needle portion, and this is the syringe portion (indicates).

Q. All right. Now, if you would, put the needle down.

A. (Complies.)

Q. If it were just that in your right hand, just the syringe, that doesn't have any sharp to it, does it?

A. No.

Q. Okay. What if we were able to make the needle disappear into that syringe?

A. It would be a lot safer.

Q. Okay. Show the jury why using Mr. Shaw's technology.

A. Oh, certainly.

Q. I may need a real shot.

A. Same process. I would get the site prepared.

Q. Let's scoot right down here so everybody can see what we are so proud of.

A. I would never give a shot to someone standing up, by the way.

Q. You're fine.

A. I would give my injection, inject my medication.

Q. And it popped.

A. And now the needle is back inside the syringe.

Q. Why -- why, now, is this one like -- what is the difference between these two?

A. This one has been used.

Q. Well, I understand, but what's it got inside of it?

A. Oh, they are both contaminated. I mean, this one has the contaminated sharp all enclosed inside the syringe; this one, we took the needle off.

Q. So let's go back to our real-world example. Here I am with my arm bleeding, and you've just finished up giving me my shot with Mr. Shaw's invention.
Now what do you do?
A. Well, I -- it would actually be easy for me to set that down, put a Band-Aid on, and then put that in the sharps container.
Q. Is that going to hurt anybody now?
A. No.
Q. Why not?
A. The sharp is -- the dirty needle is all enclosed inside the syringe.
Q. Okay. One other question.
A. I'm through.
Q. That's good. And that didn't hurt at all.
Thank you. Here's that.
The Shaw technology that you show every day of your working life, does it allow for a reusable needle?
A. No.
Q. How -- how does it prevent that?
A. Because when the medication is injected, when the plunger's fully depressed, the needle retracts inside, and there's no way to reuse it.
Q. Okay. Now, on Friday, Mr. Beck showed the jury a picture of a lot of BD's safety products, and a

fair number of them had some kind of what I call an external device, like a sheath or a shield or a tube, to go around the dirty needle.

Have you seen products like that?

A. Yes, I have.

Q. How many hands do you have to have to manipulate that kind of a safety product?

A. Well, I guess about three, because if you're taking care of your patient and taking care of that patient you just gave an injection to, it still would take two hands to, for example, to push a sheath forward on that.

Q. And when you get done with that kind of safety idea, are you doing anything different, really, than recapping?

MS. PIROZZOLO: Objection, Your Honor.

THE COURT: Based on what?

MS. PIROZZOLO: Foundation.

THE COURT: Mr. Carroll, why don't you establish a foundation?

MR. CARROLL: Thank you, Your Honor.

Q. (By Mr. Carroll) Based on your experience, you've told the jury that recapping is dangerous and against the law.

Are these external sheaths where you have to manipulate them, any different in your experience than recapping?

MS. PIROZZOLO: Objection, Your Honor.

THE COURT: Overruled.

A. No. It's covering up a dirty needle.

Q. (By Mr. Carroll) Okay. How is the Shaw invention different in your experience? I know you're not -- you're not an engineer.

A. No, I'm not.

Q. Well, congratulations.

From your experience and your understanding as a nurse who actually uses the Shaw technology, how is it different from covering up a dirty needle?

A. The big difference is that it just automatically takes that needle out of the way.

There's -- it comes right from the patient, goes right into that syringe, so you never get exposed to it at all. You never have to take the needle out and be exposed to that dirty sharp even for an instant.

Q. Mr. Beck told the jury on Friday that some nurses like to be able to change a needle from one syringe to another syringe.

Is that possible with the Shaw technology?

A. No, it's not.

Q. Why not?

A. Because the needle is built into the syringe.

Q. Is that a problem for you as a 24-year practicing nurse?

A. No.

Q. Why not?

A. Because it's unnecessary to do, and there's actually some risks. If you take that needle off, there is a risk that the syringe or the needle or the medication inside can become contaminated.

And there have been organizations like the CDC, the Centers for Disease Control, that has said it's not necessary.

Q. Have you ever heard the term closed system, closed system insofar as giving shots?

A. Yes. The term, closed system, is used really in a lot of medical devices or technologies, because the more you can keep it closed, the less risk there is for it to get contaminated, to get some kind of bacteria on it that could harm the patient.

Q. Make somebody sick for years later?

A. Yes.

Q. Ms. Duesman, I told the jury that you and your husband kind of voted with your pocketbook.

Is that true?

A. Yes, we did.

Q. Do you own shares or stock in Retractable Technologies Inc.
A. Yes, I do -- yes, we do.
Q. So you've got a horse in this race, so to speak?
A. Yes.
Q. Are you telling -- have you told the jury anything today that you don't tell people every day of your professional life?
A. No.
Q. I mean, this is what you do for a living.
A. Yes, it is.
Q. Do you believe in your product?
A. Absolutely.
Q. Today, does the industry still put out dangerous needles?
A. Yes.
Q. The ones just like you gave my first shot with?
A. Yes.
Q. About how many?
A. Millions and millions.
Q. Thank you, ma'am.
MR. CARROLL: I pass Ms. Duesman, Your Honor.

THE COURT: Cross-examination.

CROSS-EXAMINATION

BY MS. PIROZZOLO:

Q. Good morning, Ms. Duesman.
A. Good morning.
Q. You are the corporate representative of RTI here today?
A. Yes.
Q. And that means you are only appearing here on behalf of the corporation?
A. Yes.
Q. Okay. And you've been at RTI since 1996, you said?
A. Yes.
Q. And you're a stockholder in the company?
A. Yes.
Q. Now, you're a registered nurse, correct?
A. Yes.
Q. And your work at RTI has focused on the clinical aspects of the VanishPoint syringe, correct?
A. Yes.
Q. And your testimony here today has focused on the clinical aspect of the VanishPoint syringe, correct?
A. Yes.
Q. But you've said, I think on your direct, that

you're not an engineer; is that right?
A. No, I am not.
Q. Okay. And you didn't design the retraction mechanism in the VanishPoint syringe, correct?
A. No, I did not.
Q. And you're not an inventor on the patents being asserted in this case; is that right?
A. That's correct.
Q. Okay. Mr. Shaw is the sole inventor on those patents; is that right?
A. Yes.
Q. And this is a patent infringement case, correct?
A. Yes.
Q. And in this case, RTI is accusing Becton Dickinson of infringing three patents, correct?
A. Yes.
Q. But in your direct testimony, you didn't discuss any of the three patents at issue in this case, correct?
A. That's correct.
Q. Okay. You didn't discuss the specific claims of those patents that RTI is asserting against Becton Dickinson, correct?
A. That's correct.

Q. And you didn't discuss the type of retraction mechanism that is claimed in those patents, correct?
A. Yes.
Q. Now, the BD products accused of infringement here today are the 3ml Integra and the 1ml Integra, correct?
A. Yes.
Q. But during your testimony, you didn't discuss the retraction mechanism of those two syringes, correct?
A. Yes.
Q. And, in fact, you don't know how the retraction mechanism of those syringes work, correct?
A. I'm not an engineer, so I don't have a complete understanding of that.
Q. So in this case, the jury is going to be asked to decide whether the BD products infringes the RTI patents, correct?
A. Yes.
Q. And you really can't shed any light on that, can you?
A. No. That's -- that's not what I'm here for.
Q. And you aren't familiar with other retractable syringes that existed in patents before Mr. Shaw filed his patent in this case, correct?
A. That's correct.

Q. So you can't really shed any light on the issue of whether Mr. Shaw's patents are valid in light of the prior art, correct?
A. That's correct.
Q. Now, you talked earlier about how the VanishPoint works. You activate the retraction mechanism in the patient, correct?
A. Correct.
Q. Okay. So if the VanishPoint is operated as recommended, the nurse or clinician fully depresses the plunger while the syringe is in the patient, correct?
A. While the needle is in the patient.
Q. The needle is in the patient.
A. Yes.
Q. Thank you.
Now, the Integra syringes can be activated in or out of the patient, correct?
A. My understanding is that is -- that's on the instructions for use.
Q. Okay. The instructions are that the clinician can operate the retraction mechanism in or out of the patient, correct.
A. Yes.
Q. Okay. So if clinicians want to operate the retraction mechanism out of the patient, they have the

option to choose Integra, correct?

A. I'm sorry. I don't know that I understand that really well.

The instructions say they can do it either way, so...

Q. And so --

A. So they could choose that.

Q. -- Integra gives them that choice, correct?

A. Yes.

Q. And VanishPoint doesn't, correct?

A. No.

Q. Now, you talked about the attached needle in the VanishPoint syringe, correct?

A. Yes.

Q. So clinicians can't remove the needle from the VanishPoint syringe?

A. Correct.

Q. Okay. In contrast, BD's Integra 3mL syringe, you can detach the needles from the syringe, correct?

A. Yes.

Q. And RTI hasn't done any study to determine whether detachable -- customers prefer detachable needles, correct?

A. No.

Q. Now, you talked a little bit about other

syringes on the safety market, correct?
A. Yes.
Q. VanishPoint competes with those syringes, correct?
A. Yes.
Q. Okay. It competes with the BD Integra; is that right?
A. Yes.
Q. It competes with the BD SafetyGlide, correct?
A. Yes.
Q. It competes with the BD Eclipse safety product, correct?
A. Yes.
Q. It competes with the BD safety lock product, correct?
A. Yes.
Q. It competes with -- against all the safety -- different types of safety syringes that are on the market, correct?
A. Yes.
Q. So that means sometimes customers choose other safety products over VanishPoint, correct?
A. Yes.
Q. And those are all safety products that are approved by the FDA; is that right?

A. Well, the standards are approved by the FDA, but, yes, they are.

Q. So the FDA has determined that those products are safe and effective, correct?

A. I'm not sure that the FDA determines whether they prevent needlestick injuries, but the FDA has permitted them to be marketed.

Q. The FDA has approved those products for use --

A. For use --

Q. -- by clinicians in this country --

A. Yes.

Q. -- correct?

A. Yes.

Q. Now, you talked about RTI's manufacturing facilities in Little Elm; is that right?

A. Yes.

Q. RTI has manufacturing facilities elsewhere, correct?

A. Yes.

Q. Okay. Where -- where are the other manufacturing facilities?

A. We have another contract manufacturer in China.

Q. Okay. And what percentage of RTI's syringes are manufactured in China?

A. I don't know. I'm really not sure.
Q. Now, Ms. Duesman, you're familiar with the ECRI organization?
A. Yes.
Q. Okay. And that is a nonprofit organization that evaluates medical devices, correct?
A. Yes.
MS. PIROZZOLO: And I want to put up on the slide projector --
Q. (By Ms. Pirozzolo) And I can give you a copy of an ECRI report.
THE WITNESS: Thank you.
Q. (By Ms. Pirozzolo) Now, in August of 2007, ECRI issued a report on needlestick prevention devices, correct?
A. Yes.
Q. And in that report, ECRI rated the BD Integra product, correct?
A. Yes.
MS. PIROZZOLO: Can we go to that page, please.
Q. (By Ms. Pirozzolo) And ECRI evaluated the BD Integra product, correct?
A. Yes.
Q. And ECRI rated the BD Integra product

preferred; is that right?
A. Yes.
Q. Okay. And in the report, ECRI stated that the BD Integra product offered excellent protection against needlesticks, correct?
A. Yes.
Q. And is easy to use, correct?
A. Correct.
Q. Okay. Now, VanishPoint is not a hundred-percent effective, correct?
A. If it's activated in the patients and then retracted, there's no way you can be exposed to it.
Q. But needlesticks have occurred with the VanishPoint syringe, correct?
A. Yes.
MS. PIROZZOLO: I have no further questions.
THE COURT: Redirect?
MR. CARROLL: Just briefly, Your Honor.

REDIRECT EXAMINATION

BY MR. CARROLL:

Q. I want to ask you about that study that we were just looking at.
MR. CARROLL: Ms. Martin, can you turn me on?

Q. (By Mr. Carroll) We just got -- you just talked about this study, and over here it says top choices, BD and RTI. But I want you to look down here where it says not good choices.

Any of our products listed on not good choices?

A. No, sir.

Q. Any of BD's listed on not good choices?

A. Yes.

Q. BD safety lock syringe, and the document that the BD lawyer just asked you about says: We don't advise the purchase of these products, all of which use barrel shields.

A. That's correct.

Q. Do they still sell those things?

A. Yes.

Q. Is that one of the products that Mr. Beck showed the jury on Friday, bragging about his company?

A. Yes.

Q. And the very document that the BD lawyer asked you about says don't buy this, and they still sell it?

A. Yes.

Q. I want to ask you -- excuse me -- one last question.

Do you have one of your props there?

MR. CARROLL: Your Honor, may I come around?

THE COURT: Yes.

MR. CARROLL: Thank you.

THE COURT: You don't necessarily have to ask permission. I know it's a --

MR. CARROLL: Old habits die hard, Judge.

Q. (By Mr. Carroll) Let me have a syringe and a needle, just the one that's --

A. Which one?

Q. -- unguarded, so to speak.

A. Sure.

Q. Now, you were asked a question about the difference between the accused retractable and our patented technology. And I think you testified that they advise -- that they said that you could activate it in or out of the patient.

A. Yes.

Q. That's theirs, the one we're suing, correct?

A. Correct.

Q. Now, ours you can't activate, other than in the patient when you finish giving the shot, correct?

A. When you -- when you finish giving the shot, it automatically activates.

Q. It's automatic. Part of the shot?

A. Correct.
Q. Here's my question: What possible sense does it make to you, as a 24-year practicing nurse, that you would tout as a safety feature anything that allowed you to come out of a patient's body with a dirty needle?
A. None.
Q. What sense does that make?
A. None.
Q. And they brag on that, right?
A. Yes.
Q. Okay. That's all I have. Thank you, ma'am.
THE COURT: Recross.

RECROSS-EXAMINATION

BY MS. PIROZZOLO:

Q. Just one question.
MS. PIROZZOLO: Dennis, could you go to Page 240 of Exhibit -- Plaintiff's Exhibit 264?
Could you focus in on the top of the right-hand column where it says also good candidates?
Q. (By Ms. Pirozzolo) Also, good candidates, Ms. Duesman, do you see the BD Eclipse needle rated as a good candidate by RTI -- I mean, ECRI?
A. Yes.
Q. And the BD safety slide -- SafetyGlide syringe is rated as a good candidate by ECRI, correct?

A. Yes.

MS. PIROZZOLO: No further questions.

MR. CARROLL: No further questions.

THE COURT: You may step down.

Call your next witness.

MR. BOWLES: With the Court's permission, Plaintiff calls Mr. Neil Sheehan.

THE COURT: If you'll please come around.

COURTROOM DEPUTY: If you'll raise your right hand.

(Witness sworn.)

NEIL SHEEHAN, PLAINTIFF'S WITNESS, SWORN

DIRECT EXAMINATION

BY MR. HARDIN:

Q. Good morning, Mr. Sheehan.

A. Good morning, sir.

Q. Could you please state your full name and current occupation for the record?

A. My name is Neil Sheehan, N-E-I-L, S-H-E-E-H-A-N, and I'm a consulting engineer in the field of medical devices.

Q. What's your educational background, Mr. Sheehan?

A. I have a Bachelor of Science in mechanical engineering from Villanova University from 1968. I graduated with the highest honors, summa cum laude. I did some graduate work at Harvard, and later on, did some additional work at the University of California in organic -- organic chemistry and biology.

Q. And you said you're a consultant in the medical device field, sir?

A. That is correct.

Q. How long have you been working in the medical device field?

A. A little over a third of a century. About 34 years.

Q. And are you a member of any professional associations, sir?

A. Yes. I am a senior member in the Society of Plastics Engineers.

Q. What -- just for folks that may not have heard about the Society of Plastics Engineers? Can you tell what that society's interest is?

A. The society's interest is plastics, just like in that film The Graduate in the '60s.

And so we concern ourselves with plastics, how they're made, how they're used, et cetera. My particular concern is how they're used in the medical device field.

Q. What does a consulting engineer do in the medical product field?

A. Well, speaking for myself, I do -- I do a number of things. Sometimes I'll be asked by a company to come in and design something from scratch.

Gee, we need a new syringe design. We need a new IV set. We need a new dialysis device. We need a new defibrillator. And then I'll come in and I'll help design that from scratch from the very beginning.

And then other times I'm brought in because they're having problems with their products. It doesn't work. They can't manufacture it. And perhaps I can figure out ways to help them manufacture it better, help improve the performance, and make it a better -- better product.

And other times I'm asked to come for startups, and this is one of the pleasures of being a senior member of my group is, I get to help young folks start companies. I do that for free and help them -- help them get going. It's kind of fun.

Q. Now, do you often make yourself available as an expert witness in pieces of litigation like this that deal with medical technology?

A. Yes, I do, sir.

Q. You mentioned that sometimes you help a company who had developed a product figure out a way to manufacture it.

If the product's already designed, I mean, if we already have a drawing, it's all set up, why would they need any assistance from you? I mean, if it's all -- if it's all set up and the drawings are on the boards?

A. That's a very good question. Just because you can draw it does not mean you can make it, and that's especially true when it comes to plastic things.

What you need to know and especially a process called injection molding -- it's how this cup is made. They squirt molten plastic into a mold, and then it cools and out pops this -- actually, out pops a lot of them (indicating).

And so -- I forgot the -- I'm sorry. I forgot the beginning of the question.

Q. Why would they need your assistance?

A. I'm sorry. I'm just spacing out here. Excuse me a second.

Q. If we have a drawing for that --

A. Oh, right, the drawing. I'm sorry.

Q. -- and I have a drawing for the cup and I'm the manufacturer of the cup, why would I need to come talk to you about it?

A. Sorry. Little claustrophobia.

Just because you can draw it does not mean that you can make it. And so you can draw something that's impossible to make. You, for instance, can draw a ball, a tennis ball, and say, okay, look, I've drawn this tennis ball. I have an outside and an inside.

And then -- but there's no way to mold that. There's no way to have steel on the inside of the ball and steel on the outside of the ball and then be able to remove the steel.

So one must be very careful in how one -- that's a very simple example, but a lot of the patents that are out there have designs that simply cannot be made either because they can't be molded or they can't be assembled.

And if they can be, it's going to be expensive and difficult and a problem.

Q. What is your experience with molding technology?

A. Oh, goodness. I've been involved with molding plastic parts in the medical device field since day one in my experience with the medical device field. So that would be for 34 years.

Q. Now, we're going to talk about, in this case, quite extensively the terms friction and clamping, but I'm going to use a different term --

A. Sure.
Q. -- for you and ask you if you find any relation to those terms that we're going to talk a lot about in this case.
Can you tell the jury what a press fit is?
A. A press fit, which is also known as an interference fit, is when you take something that's larger that -- you take a shaft -- it's like a cork in a wine bottle. You have an object that's larger being pressed into a smaller hole. Sometimes this is done with metal, and sometimes it's done with plastic.
So the idea is, you're pushing in a cork or a rod that's larger than the hole it's going into. So as a consequence, the part that's on the inside is all scrunched and it's kind of pushing out, and the part on the outside is feeling kind of intruded upon and it's pushing back in, and that's what is known as an interference fit.
And what holds that from coming out is friction. And that's what press fit is.
Q. Now, when you have a press fit, do the surfaces have to be completely smooth?
A. Ideally -- ideally, you would like them that way, but no. From time to time, there will be bumps, rings, and other features inside, but the primary -- the

essence of what's holding the two parts together is the interference fit, and that leads to the friction, which holds it together.

Q. Now, you mentioned to the jury that you have done engineering work in the medical device field. And this is a patent case.

A. Yes.

Q. Do you -- do you have any experience in patenting or patents?

A. Yes. Excuse me. I'm the named inventor on 37 medical device patents.

Q. So are you sole inventor on those, co-inventor on some?

A. Some sole inventor; some co-inventor.

Q. Okay. So in this patent case and from a technology standpoint, is this case about what holds the needle in the projected position before the spring pushes it back, or is it about the thing that releases it?

A. It's about what holds it in place, not what releases it.

Q. And just broadly, what is required about how the needle gets released, how the spring shoves the needle back into the syringe?

A. The only thing that's required is that the friction or clamping that's holding the needle -- the needle in the -- the needle holder in the upright position, the only thing that's important is that that, in fact, is released, thus allowing the needle to retract and the retainer member to -- to not retract. That's the non-retractable part.

Q. And we'll get into some detail --

A. Sure.

Q. -- just in a moment, but do you have an opinion as to whether or not BD syringes work that way?

A. Do they work which way?

Q. By a release of the friction from clamping or friction that's holding the needle in a projected position.

A. They do, sir.

Q. Is that true for both products? We've accused both products. We've accused a small one called the 1ml and a larger one called a 3ml.

A. That's correct.

Q. And does that fact meet at least some of the requirements of the claims that define Mr. Shaw's patented inventions?

A. Yes, sir.

Q. Are there other requirements of those claims?

A. Yes. Each claim consists -- and these are at the back of the patents. These are the numbered sections or sentences. They're really very long, run-on sentences.

Each of those sentences or claims consist of a number of separate limitations, and that fully describes what the invention is. And that's what you compare the accused product to to determine whether or not there is infringement.

Q. Okay. I want to give now sort of an overview for the jury of what you were asked to do in this case.

You were asked to come here by my client, Retractable Technologies, Inc., and did you form opinions, at our request, which you could share with the jury in this case?

A. Yes, I did.

Q. Okay. What were those opinions that you formed?

A. I was asked to form opinions regarding whether or not the 1ml and 3ml Integra syringes infringed a number of claims. There are three patents, and a number of claims from each patent are being asserted.

I was also asked to look at the issue of validity. Are these claims valid as issued? The Patent Office issues them, and they're presumed valid, but BD is free to argue that they're not.

So I took a look at that issue, and I found them to be perfectly valid without a doubt.

And then I was also asked to look at the issue of copying, whether or not BD copied Mr. Shaw's and RTI's designs.

And I think those are the three primary areas.

Q. And, again, broadly -- we're going to look at specifics, but what information did you review in order to form those opinions?

A. Oh, well, to form those opinions, I had to look at the accused products. I had to look at all -- at a number of the 1ml syringes, a number of the 3ml syringes.

I also looked at dozens and dozens of drawings associated with those products that were supplied by Becton Dickinson so I could see all the little dimensions that were in there, not just the ones that I could measure on the outside.

I also looked at the patents, the three patents-in-suit, read every word very many times, and looked through all the claims, looked at all the prior art that's cited on the face of the patent.

And that's the prior art -- and that can be patents or it can be publications -- that were either presented to the Patent Office or the Patent Office found on its own and -- and looked at before granting the patent, before granting the claims in that -- in that patent.

So I looked at all the prior art. I looked at all the prior art asserted by BD against these claims.

Of course, I looked at RTI syringes, but I -- you know, I had known about those.

Q. Any internal documents from Becton Dickinson?

A. Oh, in addition to the drawings, there are a number of memos and guide -- excuse me -- memos and guidelines and engineering documents beyond just drawings about these products.

Q. Now, do you have an opinion of whether or not the -- the main issue in the case is whether or not these two infringing products -- excuse me.

Do you have the sample products up there, samples of the BD products?

A. I do. I have a 1ml --

Q. Okay.

A. -- and the 3ml.

Q. Okay. So let's start with the 3ml. Can you open that up and hold it up so the jury will know exactly what we're accusing?

A. Sure. (Complies.)

Q. Have you formed an opinion, by comparing the structure of that device to Mr. Shaw's patent claims here, as to whether or not that device falls within the description of Mr. Shaw's patent claims?

A. Yes, I've done that analysis, and it does.

Q. Okay. And what about the 1ml, the smaller one?

A. Okay. This is a 1 milliliter, also known as a 1ml. Sometimes it's called a 1cc, which is a cubic centimeter. A milliliter is a cubic centimeter of water, so they're interchangeable. You'll hear cc and ml.

Anyway, this is the -- this is the Integra 1mL.

Q. And did you form an opinion about whether or not that product -- as it's structured from looking at the drawings and your study of it, whether that product also falls within the claim language, the definition of claims that are contained in Mr. Shaw's patents?

A. Yes. I did a similar study for this one, compared it to the claims that are being asserted against the 1ml syringe, the 1ml Integra syringe, and found this, too, to infringe.

Q. Did you form an opinion, from reviewing the BD documents, as to whether or not you believe that BD engineers copied features of Mr. Shaw's inventions into those products?

A. Yes. It is my belief that BD engineers copied features from Mr. Shaw's inventions into those two products.

Q. Okay. And finally, in review of the BD documents, did you see any documents containing opinions from BD lawyers that asserted that the patents are invalid or not infringed?

A. I don't recall seeing any such document.

Q. Okay. Now, before we go back to what the main part of this case is, which is going to be this comparison of each of these pieces of property called claims to each of those devices, as sort of a background so -- before we get there, you said you studied Mr. Shaw's patent in depth?

A. Yes, all three of them.

Q. Okay. And can you give the jury -- with your experience, 37 patents and 25 years in the field, can you give the jury your general impression of Mr. Shaw's patents?

A. Actually, it's 34 years in the field.

Q. Okay. Thank you.

A. Thank you for making me younger.

Mr. Shaw is the inventor of three particular patents, what are the called the '077, the '224, and the

'733.

The '077 patent is essentially about a contamination containment notion having to do with safely tucking away the plunger, also aspects of venting to prevent splatter, and that's generally the area of concern or the bailiwick of the '077 patent.

The '733 patent concerns itself -- or the '077 is being asserted against the 3ml product, just against the larger -- the larger product.

The '224 patent is -- concerns itself with how it works, how does this invention work. And that's being asserted, generally speaking, against both the 1ml and the 3ml.

And, finally, the '733 patent really addresses an assembly method and the syringe that's made by that assembly method. And mostly, it has to do with everything being loaded from behind, which is a terrific way to assemble a product, especially automatically, with automatic machinery.

And those claims are being asserted against the 1ml product, Integra product.

Q. If you were a teacher on a class in medical devices and patents, what would you give Mr. Shaw's patents for a grade?

A. A plus.

Q. Why is that?

A. These are -- these are some of the most impressive patents I've read, and I've read probably thousands of patents.

And the reason is, the inventions disclosed in these patents are so clever and so important for a number of reasons.

One, he did a number of nonintuitive things. In other words, he thought outside the box. Everyone's heard that phrase outside the box. Well, that's what this gentleman did.

The other thing is, he recognized that syringes -- it may seem obvious as we sit here now, but syringes are not just mechanical things. They're hydraulic things. And one has to take into account what happens when there's fluid inside, the hydraulic pressures and issues like that.

And another thing he did was, against conventional thinking, he created a press fit design for holding in his retainer piece that most engineers -- and I would count myself among them at the time, thinking, oh, my gosh, that will never work and that, my goodness, you're going to have to control tolerances so tightly, and this is going to be tough to do.

And he sagely realized that these two pieces of material -- remember, the cork stuck in the bottle -- that these two are going to come to an accommodation, and they're going to fit -- they're all -- in the end, they're all -- whether it's a slightly fatter cork or a skinnier cork, in the end, they're going to fit together and accommodate each other.

The barrel of a syringe is not so rigid as a wine bottle.

And so those are just some of the highlights. I mean, I was -- you know, I have 37 patents, and I really appreciate great ideas, and I was -- I was very, very struck by his invention.

Q. I think the Judge will instruct the jury at the end of the case, when we talk about the issue of whether Mr. Shaw's patents are valid, whether they actually did something that wasn't known or obvious in the art, that we have to look at that, not from today's perspective, but rather from the perspective when Mr. Shaw filed his patent application in 1995.

Now, were you involved in the art in 1995? Were you a person that was working there?

A. Yes, I was.

Q. Okay. And in the 1990s -- let's take the early 1990s. I think the evidence will show Mr. Shaw began working on this in about 1989 and worked through all the way to 1997 on the patents here.

In the late '80s, early '90s, just so we get an idea of who was working on these problems, can you tell the jury what kinds of people were -- were drawing on pieces of paper and putting -- setting forth their ideas of syringes, and in particular, retractable syringes?

A. Sure. What's very interesting about this whole issue about safety syringes and protecting healthcare workers, it really galvanized a lot of people.

Sadly, because of the HIV epidemic and AIDS, the resulting infection and condition, because that was just so horrible, and Hepatitis C -- actually, more virulent, 10 times more virulent, is my recollection -- because of all of that was going on, a lot of people rushed to solve the problem.

Okay. We got people getting stuck by needles accidentally, nice nurses who were just doing their job, and then they get stuck by a needle, and guess what? They got AIDS. And where is the justice in that?

So a lot of people tried to solve this problem. And for the most part, my understanding was, for very altruistic reasons -- there are business reasons, too, of course, but it's a win/win situation.

But if you look at the people -- and there were hundreds. By the time Mr. Shaw filed this patent, there were more than a thousand patents that had already existed, had been issued, for safety-related devices in connection with needles -- accidental needlesticks, sharps injuries.

So a lot of people were busy. And the people -- the type of people, it ranged from nurses, doctors, folks who had never designed a medical device in their lives, had seen something on TV and went, oh, my God, I can figure that out, or I'd sure like to try. There were folks -- you know, there were auto mechanics. There were just all kinds of people mostly -- like in the computer field, the next invention, you know, like the iPhone, is not going to come from some -- some nice person working at a gas station. They just don't know about it.

And -- and so you're not -- you're not going to see everybody jumping into that area.

But when it came to this needle safety, everybody could relate to it. Everybody -- everybody gets a flu shot, or everybody has had some kind of shot or knows a diabetic in the family. My dad was a Type I diabetic, so I've been around needles for a long, long time.

But everybody jumped out and tried to solve the problem. So it was a very broad range of people who were trying, trying to design solutions.

Q. So do you have a -- sort of a summary? Have you looked at documents or anything else to try to further educate your opinion about the level of skill of folks on a -- sort of an average level of skill of folks working in this field?

A. Well, the average level of -- of skill was -- was -- was below what one would normally expect for a traditional medical device.

Q. And that is because we had all these folks who might not have engineering degrees but were trying anyway?

A. That's exactly right.

Q. Okay. And we're going to talk today in detail about Mr. Shaw's patent and its claims, because that's, again, the reason we're here. But before we get there, we heard in opening statement a little bit about a couple of patents that came before Mr. Shaw's.

Mr. Beck put up about three or four, five, six patents to show that Mr. Shaw was not the first one to be issued a patent. And he showed specifically to this jury -- in addition to Mr. Shaw's patent, he showed them a patent from a Mr. McGary and a patent from a fellow named Mr. Gillespie.

Were those the three -- were those -- was Gillespie and -- I think Gillespie and McGary were both issued patents before Mr. Shaw. Were those the first three patents on retractable syringes?

A. Oh, goodness. Goodness, no. Those are just a couple of trees in the forest. The forest goes -- goes back hundreds of patents, hundreds of patents before those.

Q. And did some of those earlier patents on the general idea of retractable syringes, having a needle that would come back in the barrel, did they -- did they demonstrate the idea of having springs?

A. Oh, yeah, sure. Springs. No pun intended, the first thing that springs to mind when you want to retract something is, hey, I'll use a spring. And the earliest ones, of course, used springs.

Q. And did some of them have -- they had plungers, I take it?

A. Yes. A syringe -- a necessary part of a syringe is the plunger that pushes the medicine and medication into the person.

Q. And did some of them have vents and handles?

A. Not many but a couple.

Q. Okay. And so there were a lot of these features -- would you say that some of the features, individual features, that Mr. Shaw ended up placing in his claims, the individual pieces were sort of in these earlier patents?

A. Oh, sure. Remember, a patent claim is a list of many different limitations and components. Many of those individually and separately preexisted. Of course, finger grips preexisted, and you'll see those in the claims. But there are a number of things that preexisted.

What is important is the novel combination of these things. And that's -- that's the essence of -- at least part of the essence of what Mr. Shaw did.

Q. Now, you looked at all those earlier designs, and you've looked at -- pretty hard at what's available in the marketplace and even the history a little bit.

A. Yes.

Q. So did you find any of those earlier designs -- in all those hundreds of patents, did you find any of those earlier designs on paper ever made it into a plastic object that you could actually provide a shot to somebody with and then have the needle safely retract?

A. Not a single one. Not one was ever made, and for very good reason. As they say, when you look at these patents, you can see, oops, this person, although well intentioned, didn't realize that you can't make something like that, or that's going to take too many parts, or it's going to be too difficult, or you're going to have to glue a lot of things.

That would be the reasons.

Q. Now, the jurors have Mr. Shaw's patents in their notebooks.

A. Yes.

Q. And on the front page of those patents, there's a listing of other patents.

And can you tell the jury what that is, what that listing of other patents on the front pages of Mr. Shaw's patent is?

A. Sure. If you -- I assume they're in chronological order?

Q. I believe so.

A. So --

(Juror giving her notebook to witness.)

THE WITNESS: Oh, I don't know that I'm allowed to go there.

A. The earliest patent is the --

Q. (By Mr. Hardin) I think it's the '733.

A. It is the '733. Okay.

If you turn to the patent that begins -- no, sorry -- that ends with the three numbers, '733 -- oh, I have the same tab -- I'm sorry -- apparently. Thank you, sir.

So it looks like it's Tab 3, and the number is 5. Up in the right-hand corner, beneath the bar code is a 5,632,733.

Now, interestingly, what that means is that's the 5 millionth, 632nd, 733rd patent issued since the very first patent, since Thomas Jefferson was the commissioner of patents.

Sorry. There's that one. That's his earliest one. That issues in 1997. It's filed for in '95.

And on the front page, you see on the left, before the -- above the picture, it says references cited. This is after the certificate fancy page. That's just -- that goes on the wall. That goes in a frame.

You're looking at -- the actual page is this page right here (indicating). This is what's called the cover page. And the important part about the cover page, at least for now, is this list of pieces of other prior art. These are other patents.

So -- so -- and there are also some foreign publications and documents.

So what happens is -- and -- and -- and the inventor has the duty of candor, an ongoing duty of candor -- and I know about that, because I've gotten 37 patents -- to tell the Patent Office, hey, these are -- these are some prior art things I know about that I think you should look at, in all fairness.

And so you see that the Patent Office looked at all of these pieces of prior art before issuing the patent claims associated with this first patent.

Q. And, Mr. -- Mr. Sheehan, even with all those patents, and when Mr. Shaw was filing his patent application in 1995, I think the earliest one here, was there still a need for this kind of invention where you could actually give a shot to someone and have the needle retract?

A. Absolutely.

Q. Now, did you see any documents in the materials you looked at from the Becton Dickinson side of the case from the documents --

THE COURT: Why don't we, before we go into that, take our morning break.

MR. HARDIN: Oh, yes, Your Honor.

THE COURT: We'll be in recess 15 to 20 minutes.

COURT SECURITY OFFICER: All rise.

(Jury out.)

(Recess.)
COURT SECURITY OFFICER: All rise.
(Jury in.)
THE COURT: Please be seated.
You may continue your direct examination.
MR. HARDIN: Thank you, Your Honor.
Q. (By Mr. Hardin) Mr. Sheehan, just before the break, we were -- I had asked you whether or not, even with all of these patents -- prior patents relating to safety syringes and even retractable syringes, if there was still a need in the early or mid-'90s, and in particular, if you had seen any document in -- from the Becton Dickinson documents that confirm that.
A. Yes, sir, I did.
MR. HARDIN: Can I see --
A. Yes, sir, there was a need, and yes, sir, I did see a document.
MR. HARDIN: Can I see Exhibit 22, please.
Q. (By Mr. Hardin) Is this the document that you're referring to, sir?
A. Yes, sir, it is. July -- yes -- 1992, yes.
Q. And what is -- what about this document confirmed to you that there was still a need for a retractable -- there was a recognized need for a

retractable syringe in the '90s?

A. Well, 1992, Becton Dickinson does this survey, and the research verified the concept of the retractable needle safety syringe indicating strong preference for the product among current safety syringe users and non-users.

And down here, you can see it's 52 to 39 preference for retractable, according to BD's own studies in 1992.

Q. And had at least some of these prior patents that we discussed already issued by that time?

A. Of course, yes.

Q. Does Becton Dickinson, to your understanding -- let me ask the question this way: From your review of the Becton Dickinson documents, did it appear to you that Becton Dickinson engineers attempted to solve this problem?

A. Yes. There's a document discussing about how they did make an attempt and, in fact, tried their hardest.

Q. Okay.

MR. HARDIN: Can I see Exhibit 55, please.

A. This is the document --

THE WITNESS: It's a little hard to see.

There you go.

A. This is a document called Rethink Retractables. And my understanding of the document is, it's an internal document sent from BD headquarters out to the sales and marketing folks about why you should -- sort of a talk against -- you should -- you should say retractables aren't good.

And it says here that Becton Dickinson engineers worked very hard trying to make this idea work for us, but we could never get a retractable needle syringe to perform to the standards, et cetera.

So by this date, they had already tried to do it and -- and couldn't do it and were basically asking their folks, go out there and tell the market, hey, it can't be done. You know, buy our stuff, is essentially the message?

Q. (By Mr. Hardin) Is there anything interesting you find about the date of this document and the dates of Mr. Shaw's patents that are here in this case?

A. Yeah. This is -- this is -- this is uncanny. Eight days after this letter was written, Mr. Shaw filed his first patent application and the string of applications that led to these three patents showing that the impossible was, in fact, possible.

Q. Now, we're going to get to these specific claim terms and spend some time with them and compare them to these accused devices, but what -- what do you find in general that was different about Mr. Shaw's inventions as compared to all those earlier designs for a retracting syringe?

A. Well, Mr. Shaw's VanishPoint syringe has the distinction of being the only one that was ever made that ever worked that ever saved a life.

Q. Now, how did Mr. Shaw's approach -- and so all these folks were trying to solve essentially the same problem. How did Mr. Shaw's approach differ from all those other folks' approach, in your opinion?

A. Well, as I mentioned earlier, Mr. Shaw recognized that this was not just a mechanical problem to try to solve, it was a hydraulic problem. It was also a materials problem in the sense of how materials behave.

And it was also a recognition of the accumulation of forces that are required to activate a syringe, to deliver the medication and then activate the safety syringe. That force can never be so high that the smallest nurse can't activate it. If you can't make it safe, then it's -- then it's no good.

But finding that is the notion that inside of these syringes, believe it or not, is something on the order of a hundred psi of pressure or more than three times your tire pressures.

And interestingly, the smaller the syringe, the higher the pressure, because the area's smaller. It's a little counterintuitive, but there's an incredible amount of pressure inside of these syringes.

And so you do not want your retraction mechanism, your safety mechanism, to be inadvertently or too early activated by that high pressure. And that's another thing that Mr. Shaw addressed in his patents.

Q. Could you -- do you have -- just so the jurors understand, you say a hundred psi. I think I said in opening three or four times a garden hose pressure.

A. Sure.

Q. Can you demonstrate for the jury -- you're talking about the pressure that's developed when the thumb is pressing against the medicine to deliver it to the patient, correct?

A. That is correct.

Q. Okay.

A. Well, that's the -- the force -- sorry. I'm filling up.

The force generated by the nurse is between 6 and 8 pounds, something like that, comfortably. And that also has to be generally the range of the activation force to activate it.

Because if it takes more than that to activate it, then you can't activate the safety syringe, the safety aspect of it.

MR. HARDIN: With -- with the Court's permission, can the witness just demonstrate how far water goes in the courtroom?

THE COURT: Yes. This is Judge Ward's courtroom. We'll go ahead.

THE WITNESS: Now, with my apologies to Ms. --

THE COURT: Why don't you go maybe -- maybe this direction.

THE WITNESS: We're still friends, okay? (Demonstrating.) There's a lot of pressure. I shot it over there, and it, you know, would have kept on. I would have had...

THE COURT: Mr. Potts, maybe we should dry it, so we don't have Judge Ward --

THE WITNESS: Sorry.

THE COURT: -- too angry at us.

MR. HARDIN: We apologize to Judge Ward in advance, Your Honor.

Q. (By Mr. Hardin) Now, you said Mr. Shaw appreciated this large pressure of force that was part of the problem of creating one of these devices.

What were -- obviously, they're may be more than one solution, but what was one of the solutions that Mr. Shaw built into his designs?

A. Well, one of -- one of the things he built into his design -- one of his designs was that there was a step-down. There was a step-down from a barrel diameter through a little transition zone and then into the nose so that the area -- the smaller you make the area, the less the force is going to be given a certain pressure.

And so it was smart to bring that down in size, number one.

Q. Okay. And does -- we're going to talk a lot about something called the retraction mechanism, the actual mechanics that pull the needle back up.

A. Yes, sir.

Q. Did Mr. Shaw recognize anything about how pressures might interact and what shouldn't be happening with the retraction mechanism?

A. Could I have a little more definition?

Q. Yes. The retraction mechanism in this case is in the front part of the device.

A. Correct. It's in the nose.

Q. Right. And does it have to act -- first of all, before we get to the retraction mechanism, do you have to have any kind of a seal in the nose of the device, in the front part of the device?

A. Oh, no. Oh, of course. Of course. Holding the spring down -- because this spring is the thing that's going to fire the needle-holder back up safely into the plunger and inside the body -- the barrel of the -- of the syringe.

So, obviously, to begin with, you have to have a seal up front. And the spring, of course, you don't want to be in the fluid path, so that's on the other side. That's on the dry side, if you will.

And then there's a -- a retainer, a needle-holder. And all that has to be sealed. Fluid can't go past that, especially when you're generating the high pressures that I just -- when I cleaned the wall.

Q. So did Mr. Shaw's invention, does it involve any way -- in any way the placement or how that seal is combined in the syringe?

A. Yes. Some of his claims address the fact that they're all installed from behind.

So much of the prior art has designs where you have to put something on in the front; you have to put something on in the back. And I'm not just talking about gluing a needle; I'm talking about serious assembly.

And one of the beauty parts -- it's in the -- it's in the '224 patent asserted against the 1ml Integra -- is that essentially everything is loaded in from behind.

And this lends itself to automatic assembly. If you've ever been around any kind of automatic assembly or seen it on TV -- there are a lot of shows that show it now. I love it. It's a joy to behold. Excuse me. And that's another aspect.

Q. And wouldn't just putting things in from behind and kind of stuffing them upfront, wouldn't that be something that would ordinarily be considered by someone?

A. Sure. I mean -- I mean, that's, you know, one of the approaches, but -- but what you have to do is be able to create a seal.

And what Mr. Shaw was able to recognize -- well, wouldn't be able to; he did -- is that he could create a seal using friction.

And in this -- I mentioned earlier, this is the kind of thing that actually when I read it, I said, oh, my gosh, that will work? I don't think so. And yeah, it does.

And so he's able to load everything from the back without having to go -- without having to push past hooks or other kinds of complicated little mechanisms. The prior art -- and that means all of those older patents -- is riddled with such, oh, complicated Rube Goldberg kind of mechanisms.

Q. Now, in addition to dealing with those hydraulic forces, you said -- you told the jury just a few minutes ago that when you get down to the end of the injection, the device has to be such that even the smallest nurse can use it, because, otherwise, if you put it in the marketplace, you have to put like for use by persons over 150 pounds or something.

A. Sure.

Q. So was that another problem that Mr. Shaw addressed?

A. Yes. Yes, absolutely.

In order to maintain a low overall force, remember, you have to do essentially three things with this safety syringe.

You have to deliver the medication. Once that's done, you have to release the seal. You have to release the needle to fly back. And then you have to make the container resistant to -- to -- to tampering or inadvertent sharps risks.

And historically, in the prior art, that consisted of three different force amounts, like boom, boom, boom, or -- and they would overlap each other. So in many ways, they were additive.

And what Mr. Shaw realized is that he could combine the first two into one piece, one piece or one assembly, and get the seal and release mechanism all at once, one force.

Q. So -- I want to stop you there --

A. Sure.

Q. -- because I want to make sure that we're getting this point correct.

So if you have a syringe and you need to seal it against this huge pressure inside, then that has to be -- that has -- that has to withstand a force, correct?

A. Correct. It has to be sturdy enough to withstand 100 to 120 psi.

Q. So when the nurse's thumb comes down and she's got all the medicine in the body, then she's got to be able to push through that somehow; something has to happen to let the needle fly back up; is that correct?

A. That's correct.

Q. And is that what you were terming release?

A. Yes. I'm sorry. That's release. When you

release the retraction mechanism so it can fire back.
Q. And so Mr. Shaw's particular retraction mechanism that was -- that he developed in these patents, what did it do with those two forces?
A. It combined them. That was the deal. At the -- at the same time that you break the seal, you also release the mechanism.
Q. Now, is there any other forces that's -- that are dealt with in these patents beyond those forces, with respect to using the needle in a way that's practical for even small hands?
A. Yes. And this is -- this is really subtle, and I love this. When you -- I can't -- this one has already been activated, so I can't get it out. So I'm going to have to open up another one. And this is a VanishPoint syringe, but it could be demonstrated on others.
But, see, this is the plunger, and, you know, I would be pushing on this, and eventually, this gets pushed -- and I'm going to activate this -- and this plunger will lodge itself, will go down inside this collar like that (demonstrating).
And you can't get at it. You can't -- I mean, if you had a pen knife, sure, you could dig it out and everything like that, but that's not the point. The

point is that it's inaccessible for grasping by some nurse who thinks, gosh, maybe I can use -- this is a new syringe. I'll use this.

Now, this -- this prevents her, deters her from doing that. And the great thing is, no extra force was needed to make it go down below that level. Sounds simple, but no one had thought of it before in this combination.

Normally, all of the -- or the other prior art devices had a locking mechanism. For instance, there was a patent mentioned, the McGary patent, that had a locking mechanism where you would go down inside, and it was supposed to push past this whole ring and try to force it in there. Well, that would give an incredible amount of force to try to overcome.

So in summary, it -- Mr. Shaw combined the first two forces into one so they weren't additive and eliminated the third force, the so-called locking force, because you don't have to lock it. You can't get at it. You know, it's like the kids. You don't have to lock the cookie jar; you just have to put it up on the shelf. You don't have to lock it; just put it on the shelf, and you can't get at it.

And that's -- I know to some that seems, gee, that's obvious, but it hadn't been done before in a retractable syringe. And it was very clever to lose that force element in the locking aspect.

Q. So instead of having to go past this lock or mechanical lock, you simply -- it simply tucks the -- the claim has -- is the word tuck in these claims anywhere?

A. No. This is a -- my shorthand for what generally happens. You bring the head -- the thumb press on the plunger down to a place where you can't get it.

Q. Okay. Now, we heard a little in the opening about something called venting, some venting?

A. Yes, sir.

Q. Did Mr. Shaw use vents and venting principles in coming up with his patents?

A. Yes, he did, and it's described in his patents.

Q. Okay. And what did Mr. Shaw -- what does Mr. Shaw describe as the reason for putting vents or venting in his products?

A. The purpose of putting vents in his product is to prevent splatter or fluid coming out of the front end of the syringe during retraction.

Now, of course, if one uses the RTI syringe properly, they're retracting -- retracting it while it's in the body. And so the risks of splatter are absolutely miniscule.

Nonetheless, there are -- the vents minimize anything that might possibly come out of the front as a consequence of any pressure that's built up as it -- as the needle slides back.

Q. Now, we talked earlier about some of the features of Mr. Shaw's inventions, and are those features -- by the way, are we going to see them in just a little while described perhaps in more precise language in the claims of these patents?

A. That is correct.

Q. Okay. And do the Becton Dickinson devices use -- there are different claims covering different devices, but do they -- do one or the other devices use those features?

A. Yes, sir.

Q. Okay. Now, we also talked about all these earlier patents that were out there.

A. Yes, sir.

Q. And do any of those earlier patents talk about venting, or as you say, pressing something down into a collar?

A. Yes. The notion of venting and the notion of tucking predate Mr. Shaw's invention. They appear in a couple of patents but never in association with the other limitations in the claim. So his combination is novel.

Q. Okay. Did the Patent Examiner know that there was a patent out there that had a hole or a vent in the plunger handle in a retractable syringe while he was looking at Mr. Shaw's patents?

A. Sure. He had the Murray patent to look at.

Q. Okay.

MR. HARDIN: Can we see that, please, Exhibit 37.

Q. (By Mr. Hardin) Is this that patent?

A. That is the Murray patent, yes.

Q. Okay. And this was one of the things the Examiner looked at before he issued Mr. Shaw's patents?

A. That's correct.

Q. Okay.

MR. HARDIN: Can we look at -- do we have a blowup of it? There we go.

Q. (By Mr. Hardin) And can you tell the jury where the vents are in this?

A. Up here -- oops, that's the blinky button. Up here you see these vent holes right there (indicating), and those vent the interior chamber of the plunger of this particular design.

Q. Now, what did Mr. Murray teach about those vents?

A. Mr. Murray teached (sic) that those holes were there as a way of reducing the pressure, not at the front end of the syringe, but inside and behind this little piston thing that came flying up, along with this part which grabbed this needle and all -- and everybody headed north.

So the purpose of these vent holes was to vent this area up here as this flew up (indicating).

Q. Did anybody, to your knowledge, in any of these prior patents ever discover what Mr. Shaw discovered; that is, that you could use vents in the back to stop the fluid from coming out the front?

A. No. He's the first, and it's described in this patent --

Q. Okay.

A. -- patents.

Q. What about the use of this collar? You said that he used this collar to reduce the forces in a retractable syringe.

Was there -- was there any use -- were there any prior patents that showed use of this collar first at all?

A. Yes. One or two disclosing -- oh, collars?

Q. Collars.
A. Collars, sure. A few of them had collars.
Q. Right. Any of those in a retractable syringe?
A. No.
Q. Okay.
MR. HARDIN: Can I see Exhibit 433.
Q. (By Mr. Hardin) Is this one of those prior patent documents?
A. Yes, it is.
Q. And does it have a collar where the plunger tucks in the back?
A. Yes. Here's a collar, and here's a plunger. And this has a bonus cap on top. And that when this is -- when it's delivered, the fluid is delivered, this tucks underneath there (indicating) ---
Q. Is this --
A. -- below that.
Q. Is this use of that little collar, is that the same use that Mr. Shaw put it to?
A. Well, to the extent that it makes it inaccessible, generally speaking, yes. But, of course, this is not a retractable syringe and nor does it have venting.
Q. And why is that -- why is that important with respect to locking and forces?

A. Remember that whole point about tucking was about reducing the locking -- removing the locking force, just taking that away. And that's -- that's the essence of -- and that in combination with the other limitations in those claims is why his patent is -- is novel.

Q. And was this -- was this document considered by the Patent Office before they gave Mr. Shaw his claims?

A. Yes. That patent was being considered by the Patent Office at the time they were reviewing Mr. Shaw's application.

Q. Okay. Let's come down -- back to one issue that we've -- came up in opening, came up several times, and will come up throughout this case, which is the use of cutters, the use of cutters or cutting in a retractable syringe.

Is it your understanding that Mr. Shaw's claims, as found by this Court, can cover -- can have within their boundaries a retractable syringe that employs a cutter?

A. Absolutely.

Q. Now, does he also have in that same patent a design that doesn't require a cutter?

A. Yes, sir.

Q. And why is that in these patents that you -- that they -- does he have separate designs?

A. Yes. Within the patent, there will often be more than one -- what's called an embodiment. And in Mr. Shaw's patents, there are three embodiments.

And one of them uses two separate pieces, a retainer and a needle-holder.

Another -- another one uses no retainer. That -- that embodiment is not in -- in discussion today.

And then the third embodiment is using a bridging portion.

So there are two primary embodiments that we're looking at today.

Oh, and here you go.

Q. So on the left, we have a graphic, and why don't you walk the jury through the graphic, again, just to describe the two different -- embodiments, is that a big word for two different designs?

A. Correct.

Q. Okay.

A. Yes. This is --

Q. Would you walk the jury through the two different designs that Mr. Shaw disclosed in his patent?

A. Certainly.

If you look here, you'll see the barrel and a little transition zone and then a nose area here (indicating). And you see that on both of them. That's common.

And here, the plunger is -- they're essentially the same plunger. The spring is the same. The actual tiny little needle that's been glued into the needle-holder, this long piece here (indicating), that's all the same.

But what's different here is, in blue here (indicating), you see a separate outside retainer member. This is a non-retractable part. This part does not retract.

Inside of it --

Q. Meaning it just doesn't come up in the barrel? Is that what you're talking --

A. Correct. It doesn't go that way. It goes this way or perhaps not move.

But when you look in here -- and I hope it's clear -- here is a cross-section of this internal needle-holder part, and you can see this is where the fluid flows down this little part here (indicating). And now between this part (indicating), the yellow needle-holder part, and the blue retainer part, there is also a friction fit.

Now we've got two friction fits. You got a friction fit between the nose and the retainer and another one between the retainer and the needle holder. That's one design.

In the other design --

Q. Excuse me.

A. Okay.

Q. But is this the design that we heard -- we saw Ms. Duesman this morning using what she called a VanishPoint syringe.

A. Yes.

Q. Is that the design that's in that syringe?

A. Correct.

Q. Okay. Now -- but in the patent, there's this other design, correct?

A. That's right. That's right. This -- this is the design used by the VanishPoint product, but that's not what we're comparing it to.

This is the other embodiment where it uses what's called a bridging portion. And the reason all of this is yellow is because all of this is the same material.

Here's that elongated needle-holder, just like before. Here's the fluid path coming down here. And now the -- and this head right here, that's the needle-holder. The skinny part going around the outside is the retainer, once again, the non-retractable part. And then this is a bridging portion, and it goes over this gap area (indicating).

You know, a bridge -- in order for there to be a bridge, it has to bridge over something, so that's the gap that it bridges over.

And this is the second embodiment. And, yeah, there's a little something right there.

Q. Okay.

A. Third embodiment but the second of these two.

Q. Now, in both of these designs, what's holding -- what's holding the needle-holder from springing back up into the syringe body?

A. What's holding it from springing back up is friction or clamping.

Q. Between that retainer member and the barrel?

A. Well, in this one, between the retainer member and the nose portion of the body; in this one, it's friction here and friction there (indicating).

Q. So we've got two friction and one friction, essentially.

A. Yes.

Q. Okay.

A. On the left, we have two friction; on the right, we have one friction.

Q. Okay. Now, is there anything in the claims -- we're going to talk -- we're going to start talking about the claims and ask the jury to follow with us as we describe how these Becton Dickinson devices fall within the scope of those claims inside those boundaries.

A. Yes, sir.

Q. And to do that, they have to compare those devices, as you have, to the words of those claims, correct?

A. That's correct.

Q. Okay. Now, is there anything in the words of those claims that says you can't release the friction using a cutter?

A. No, absolutely not.

Q. Okay. And do you see some specific part of the claim that the Court has instructed that you think leads you to that conclusion?

A. Yes. If we could look at the Court's claim construction for retainer member or continuous retainer member.

Q. Let's see. So -- so this is a -- that's kind of fuzzy, but the jurors -- and you and I can look at Tab 4. This is that page that Mr. Carroll referred to this morning as sort of the -- what the legal judge in this case has given us.

And this is the Court's orders or judgment as to what some of the words in these claims we're going to look at mean; am I correct?

A. That's absolutely correct.

Q. Okay. And which of these -- we have a list of terms on the left. It's got -- and these terms come from where, the list of terms on the left?

A. The list of terms on the left come from the claims. What happens is, either the sides have a -- meet and decide very carefully what each word actually means, and with the help of the Court, who has the final word, decides exactly what -- what a word or a phrase means for the purposes of -- of this matter.

Q. So -- so what the Court has decided these words mean are in that second column over on the right.

A. That's correct.

Q. Okay.

A. That's known as the Court's construction or interpretation of the words on the left.

Q. Now, is there a particular word or phrase here on the left that you think tells you that a syringe design that has a cutter could be still included in -- in fact, is included, in the claims of Mr. Shaw's invention?

A. Certainly. If you look at the eighth one down, it's the one that has the -- kind of the larger area called retainer member. Yeah, it's zoomed up on the screen, but it's a little fuzzy. But that will tell you which one it is.

And the language there is -- this is the Court's construction of the term retainer member: A non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until that clamping or frictional force is released.

Q. Now, does it say anything there about what has to be used to release that frictional force?

A. No, absolutely not. There's no limitation on what does that.

Q. And so as far as the wording in this claim, does it matter whether it's a cutter, whether it's cut off, broken off, pushed off?

A. No. It can be ruptured, fractured, cut, anything.

Q. Okay. Now, also in this claim term, does it say that what's -- what's holding this down there has to be exclusively friction?

A. No, it does not.

Q. What does it say on there?
A. Within -- within the same limitation?
Q. Yes.
A. Okay. Focus on the word some. It says a non-retractable part of the retraction mechanism that uses some clamping or frictional force, some clamping or frictional force. Not entirely, not 80 percent, not whatever, but some.
Q. Now, is there some -- anything else in the claims, other than a forward movement of the plunger, that's required by the claims to release this needle-holder?
A. No. That's all that's required. The forward movement of the plunger releases the needle-holder. And that's where the needle is, and that's what you need to retract.
Q. Does Mr. Shaw teach in his patents ways to release frictional holding?
A. Yes, he does.
Q. And how does he teach that can be done?
A. He teaches -- in one section of the patent, he uses the phrase to rupture, fracture, or otherwise separate.
Q. Okay.
MR. HARDIN: Can we see Exhibit 5.

Q. (By Mr. Hardin) This is the patent-in-suit, correct? This is the '733 patent-in-suit.
And in the --
A. Which Exhibit 5? Which book?
Q. I'm sorry.
A. I don't think it's 5.
Q. It's 5 in the court record, but, unfortunately, we didn't put the jury notebooks together until later. It's Exhibit 1 in the jurors' notebooks. Actually, I think it's Exhibit 3, isn't it?
A. '733 is Exhibit 1 in the jurors' notebooks, I believe.
Q. Right. Let's look at -- let's look at --
MR. HARDIN: Can we have Column 2, Lines...
There we go. Okay.
Q. (By Mr. Hardin) This is from Column 9, I believe, in the '733 patent.
Now, how does that statement in the patent relate to this issue of what's releasing?
A. Okay. Just -- just to follow along, it is in Column 9 of the '733 patent, and you have to go down to about Line 51.
Within the patents, there are these little numbers down the middle, 5, 10, 15, 20, 25, 30, and it

kind of shows you approximately where the lines are.

They don't line up so well.

But if you're looking at the '733 patent, Column 9, find the numbers in the middle, go down to sort of the 50-ish area, go to your left, and you see that 22a that's not highlighted up on the screen?

That's the end of the last sentence. That's not like a number of this area here.

Yeah, you can see that's where it comes from.

Thank you.

And now if you zoom back, we'll just take a look at the language.

And it says any tack weld connecting the separable parts at the bridging portion is ruptured, fractured, or otherwise separated so as to separate Retainer Ring 66 from Inner -- Inner Head 72a, thus releasing Needle-holder 22a from further restraint.

So, essentially, that describes -- I couldn't describe -- have said it better. That describes what I -- what I just described myself.

Q. Okay. And is cutting one way of separating?

A. Oh, sure.

Q. Now, we saw in opening statement another statement from this same patent.

MR. HARDIN: If we can, if we can look

back at Column 2 of this same patent.

Q. (By Mr. Hardin) In Column 2 of the '733 patent, there's some statements that were shown to the jury, I think, in -- either read to them or shown to them in opening where Mr. Shaw was describing what went before.

Do you remember some of those statements, sir?

A. I do.

Q. Okay.

MR. HARDIN: Do we have a blowup of those statements?

Q. (By Mr. Hardin) Okay. And in this part of the patent, Mr. Shaw is trying to express what's going on before.

A. Yes, sir.

Q. Okay. And I think in particular, if we look down about -- let's just start where the paragraph begins, okay, where it says the prior art.

You see that, sir?

A. Yes, sir, right here.

Q. It says, the prior art has not recognized retraction mechanisms -- that's this thing we're talking about, correct?

A. Right. The mechanism consists of the retainer, the needle-holder, the spring, et cetera.

That -- that is the mechanism that fires the needle-holder back.

Q. Okay. The prior art has not recognized retraction mechanisms with separable parts -- that's these parts that separate, correct?

A. Yes.

Q. -- that relies entirely on clamping or friction at a smooth-walled reduced diameter transition zone in the barrel with mating lands, which are slidably or separably released, in response to relatively low thumb pressure while having a resistance to premature retraction and high-pressure blowout resulting from high pressure produced in the fluid chamber during an injection.

Is that this concept of having to have low thumb pressure for the nurse but guarding against this high internal pressure?

A. That's exactly right. It's a great description of what I tried to describe earlier.

Q. Okay. It continues, the prior art has not recognized that such a structure can be molded as a one-piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place and steered by the narrow nose portion.

Is that this concept we described generally about the advantage of being able to mold it and then combine -- produce it or manufacture it?

A. Yes. To be able to mold the entire syringe body out of one piece -- and here, obviously, the core pin is what he's referring to -- coming up behind -- where it says the word core, we molding folks call it a core pin; a core pin that can be pulled out -- and that allows the retraction mechanism to be easily pushed into place from behind and steered by the narrow nose portion.

That's what I was trying to describe earlier. It's in the patent.

Q. Okay. And, finally, it says neither -- neither does the prior art, in such a combination, realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required having a most simple tamperproof feature and the fewest number of easily made parts.

Does that have to do with this tucking in the back, as you called it?

A. Absolutely. That's another great portion of the patent to read.

Q. Okay. Now, there was some characterization -- we talked about friction and clamping, and that is an

important part of Mr. Shaw's invention, correct?
A. That is true.
Q. But is his invention just limited to features that deal with friction and clamping?
A. Oh, goodness, no.
Q. And are these -- this venting concept and this reducing of locking pressures, are those directly related to friction?
A. No. Those are in addition to.
Q. Okay.
A. There are a number of features and aspects in his inventions, which you'll see when we eventually do get to the claims limitation by limitation, that -- that in combination are novel --
Q. Okay.
A. -- new.
Q. Now, we're just about to get to the part where we're going to talk about the infringing devices and look -- and look at them and compare the language of the claims to each of those products.
A. Yes, sir.
Q. But before we get there, there was much discussion again in opening statement about one particular patent. It's called the McGary patent.
A. I recall.

Q. Okay. And there was a suggestion that the McGary patent shows basically what Mr. Shaw's invention shows, same thing.

A. I guess they made that suggestion.

Q. Okay.

A. It's not true, but...

Q. All right. First of all, the McGary patent was one of the patents the Examiner had in front of him at the Patent Office before he gave Mr. Shaw his patent?

A. That is correct. They were well aware of it.

Q. And we're going to go through each of claims together, but before we do that, did you take a look at the McGary patent and identify the distinctions that are in the actual wording of Mr. Shaw's claims that you don't find in the McGary patent?

A. Yes, I did. I made such a comparison.

Q. Okay.

MR. HARDIN: Can we see that?

Q. (By Mr. Hardin) Okay. And are these features words in the claims of Mr. Shaw's patent that we're going to describe -- these are like pieces of the boundary; is that correct?

I've got -- we haven't got a box here. We've taken -- we've taken a leg from this claim and a leg from that claim, and in a moment, we're going to look at them all together.

But each of these statements, 1 through 10, do they come from these boundaries and descriptions in the claim?

A. Correct. These are limitations -- these are actual words from the actual claims. It will be hard -- I'm glad nobody's looking -- to find them, because they come from different claims, but it will be explained shortly.

And these are in addition to the use of friction or clamping, which is something that Mr. Shaw invented. These appear in the other asserted claims. And what I did was, I looked for these -- these appear in Mr. Shaw's inventions, and I looked to this older McGary patent, which -- to see if -- if they came from there, if they even appear in there. And I will --

Q. Okay.

A. We can go through it, if you like.

Q. Yeah. I'd like to -- I'd like you to go through them just as quickly as we can.

Number one, the plunger seal element, being restrained from sliding longitudinally along the outer wall at the plunger, that's one of the things that Mr. -- is in Mr. Shaw's patent that is not in Mr. McGary's patent?

A. That is correct. It refers to this little black part here (indicating) not being able to move on the plunger.
In McGary, it does.
Q. Okay.
MS. PIROZZOLO: Your Honor, may we approach?
THE COURT: Yes.
(Bench conference.)
MS. PIROZZOLO: I corresponded over the weekend about whether RTI was going to put on its invalidity case in its case-in-chief, and you sent back an e-mail saying --
MR. HARDIN: I said -- I said we were going to generally talk about invalidity here and would save our actual rebuttal validity case for --
MS. PIROZZOLO: We don't think you can do it twice and now you are putting on specific claim elements and putting on an invalidity case.
MR. HARDIN: I'm not putting on an invalidity case. I'm -- there was a big thing in the opening about, essentially, we're practicing Mr. McGary's patent.
What I'm showing is that his patent has elements that are not in the McGary patent, not the type

in this case.

THE COURT: Well, what was your agreement about putting on your invalidity?

MR. HARDIN: I told them that I would be talking about invalidity, but I would be change -- I would be -- I told them, I said I'm going to mention invalidity.

MS. PIROZZOLO: Mention?

THE COURT: Well --

MR. HARDIN: But I'm going to save -- obviously, I have to save my defense for after I see their case.

MS. PIROZZOLO: This is much more than mentioning, Your Honor.

MR. HARDIN: Your Honor, in the opening, you heard all --

THE COURT: I understand all about the opening.

Well, it seems like you're going way past the -- what seemed to be the agreement of the parties. So I would suggest you save this for your defense.

MR. HARDIN: Okay. That's fine.

MS. PIROZZOLO: Thank you, Your Honor.

(Bench conference concluded.)

Q. (By Mr. Hardin) So as to not get real confusing about -- because these are things from different claims. I think I said a minute ago --

A. Yeah.

Q. -- that there are several things. We are going to come back to this after we've looked at the claims themselves, okay?

A. Okay. Sure.

Q. So let's go to the claims themselves. And your opinion -- here's your actual opinion of what we're asking this jury to find, which is -- their job at the end of this case is going to be to look at the BD Integra syringes and see if they fall within the scope of claims that we're asserting in this patent -- from these patents; is that correct?

A. Yes, sir.

Q. Okay. So let's go patent by patent, if we can.

A. Yes, sir.

Q. Let's start with the '077 patent. That's the one that is at Tab 2 of the jury notebook.

And what claims are we asserting? What numbered paragraphs at the end of this patent are we asserting are infringed by Becton Dickinson -- Becton Dickinson's products?

A. RTI is asserting that Claims 10 and 25 are infringed by BD's Integra 3mL syringe.

Q. Okay.

A. And that claim, Claim 10, can be found in the patent at Column 19.

You notice there are two columns on each page, and if you go to Column 19 about halfway down, you will see the No. 10.

And the words there in the patent have been reproduced up on the slide. You don't have to follow in the patent, because they're up on the slide.

Q. Okay. And is there another claim from this patent?

We'll come back to this claim. But just as an overview, is there another claim from the patent that's being asserted against one of these --

A. Yes. Claim 25, which appears on the same page over in Column 20.

Q. Okay. So this patent -- in short, is this patent -- this patent is being asserted against one of their products; is that correct?

A. Yes. It's only being asserted against the 3ml syringe, not the 1ml but the 3ml, the larger one.

Q. Now, can you give the jury just an overview -- we're going to go through Claims 10 and Claims 25 with precision.

But the Court -- what the law requires us to do is to demonstrate to the jurors that for each line of text up there, each description of a structure, that Becton Dickinson reflects that structure.

Is that your understanding?

A. Yes, sir.

Q. And you've formed an opinion that that's what -- that is the case here?

A. That is the case.

Q. Okay. So we have to move through each of these one at a time just as if it was a separate boundary line on a piece of property until we close the loop, in your opinion anyway, and show that Becton Dickinson is inside that property?

A. That is correct.

Q. All right. So let's talk in general before we start with Claim 10. We're going to go right to that process.

But before we start with Claim 10, can you tell the jurors in general what Claim 10 protects?

A. Claim 10 and Claim 25, both part of the '077 patent, as I said earlier, concern themselves with sort of a fluid containment system. It has the -- what I call venting and tucking. And it also, in Claim 10, it concerns the venting and tucking part.

In Claim 25 -- sorry to anticipate -- it involves a two-step syringe with -- with also a similar tucking feature.

Q. Okay. So let's go to -- first of all, what did you do -- you have these words from the claim.

A. Uh-huh.

Q. What did you do to form an opinion that Becton Dickinson is using this invention as claimed?

A. Well, what I do is I take these words, and, of course, any words up there that have been construed by the Court to have special meaning, I apply that special meaning.

We just looked at retainer member as having a special meaning.

And then I compare each one of those limitations. They've been lettered just for convenience. They don't appear that way in the patent. And compare that to the actual product or drawings, engineering drawings and manufacturing drawings supplied by Becton Dickinson, represented to be the drawings that were used to make their products.

Q. Okay. And have you prepared anything to help us understand the comparison you made, the comparison between BD structures and these words of this claim?

A. Yes, sir.

Within this slide, as we go down along each one, there will be from time to time an animation or a still picture or a page out of a document. There will be some visual aids that will assist in what I'm about to explain.

Q. Okay. So let's go to your presentation on Claim 10.

And, first of all, the first thing up there says the syringe plunger handle assembly and syringe barrel combination for use in retractable syringe for injecting fluids, comprising.

So what are we -- first of all, what's that called?

A. Well, the opening line of a claim is called a preamble. It sort of defines what this thing is about generally. Is it a car? Is it a computer? Is it a new fishing tackle system?

No. It's a syringe plunger handle assembly and syringe barrel combination for use in a retractable syringe for injecting fluids, comprising.

And comprising is a special word. It means including at least the following things, and that's where all the other things come.

Comprising in patent parlance is described as an open-ended term. As long as you have all of the --

these, let's say, eight other things, you can have three additional ones. You can have -- as long as you have B through H, you can have some other things.

You can have bells and whistles and everything, but you still infringe this claim, because it says comprising. Comprising means you just have to have these at minimum, but you can have other stuff and it still infringes.

Q. Okay. So let's start with the first words, other than the general description that's required for this device to infringe.

The -- well, the term D --

A. Well, this is a picture of A, so now we can go to B.

Q. Go to B.

A. The little green check means that it's present.

MR. HARDIN: Oops, can we go back up to B?

There we go.

Q. (By Mr. Hardin) So the next thing that's required is a hollow syringe body having an elongated tubular wall, comprising an elongated barrel portion having an open back end.

Does the Integra 3mL product have that?

A. Yes. And if we could show the figure that goes with that.

This is the BD engineering drawing. Here is an image of the actual product. And now we're going to pull some parts away from it here so that you get down to the -- actually, the simplest little part, which is certainly a syringe body with an elongated tubular wall and a -- with a elongated barrel portion. And it has an open back end.

Q. Okay.

A. So this is met; this is satisfied; and we can put a green check over on the right side for that one.

There you go.

Q. Okay. An elongated -- the next one is elongated plunger disposed for reciprocation and sliding sealed contact with the barrel portion of the body. Does the 3ml have that?

A. Yes.

Here you can just see it's a pretty straightforward demonstration, the fact that the plunger is able to move back and forth within the barrel.

Q. Okay.

A. So that gets a green check mark right here.

Q. Okay.

A. Thank you.

Q. And next, the next requirement is the plunger has a tubular wall and defining a head portion in front.

A. The plunger having a tubular wall defining a head portion in the front, and we just saw that animation happen quickly while we were speaking.

Here is the head portion of the plunger, and here is the wall -- the wall of the plunger (indicates).

Q. Okay.

A. So this is also met by the Integra 3mL product.

Q. All right. And the next requirement is?

A. So there's a check.

A back-end portion carrying a thumb cap.

And here is the plunger, and there's the thumb cap, and it's just that straightforward.

So that gets a check as well.

Q. Okay. The next requirement is the hollow interior comprising a retraction cavity.

A. Yes. And that's located between the head portion and the thumb cap.

Well, you know this is the head portion; we just covered that. You know this is the thumb cap, and the retraction cavity -- and this is the part where the needle's going to go -- is right there in between.

I should -- I should point out that in these images, the front part of the barrel is not shown for simplicity's sake. That's the detachable needle system. So we're just showing this without it, just for simplicity's sake.

Q. Now, the term retraction cavity, why -- why does the term retraction cavity fit this space that you're pointing to?

A. Because that's where the needle goes along with the spring and just anything else that is going to be retracted in the process of bringing the needle -- making the needle disappear.

Q. Okay. So we can put a check mark there, I guess.

A. Yes, please.

Q. Another limitation: The thumb cap having an outer side adapted to reside in close association with the open back end of the plunger barrel when the plunger is nearly fully depressed.

Does it have that?

A. Yes. Yes, it does. Here's the thumb cap. And what we're going to do when we run the slide is we're -- the animation, we're going to see what happens and see that close association.

Q. Okay.

A. Now, that's highlighting the thumb cap and the end of the -- the open end of the collar. And there's some venting, which I'll talk about later.

And now you see here, it resides in close association, essentially, inaccessible for grasping.

Q. Okay. Is that the last of our items on this -- on this slide, I suppose?

A. Well, there's a BD document associated with this -- this is the penultimate one.

Q. Oh, this is on the close association?

A. Right.

Q. You found a BD document in -- in -- in your review that you thought bore on whether or not they were using uncapping that had an outside edge and close association?

A. Yes. In fact, this is from the BD document. This one right here is -- as you zoom in on it, and you can see just as I showed in the animation, that it is down below. And it actually says the reason it does that is to prevent manual removal of the plunger rod.

Q. So the Becton Dickinson engineers designing this wanted the thumb cap inside the collar to prevent manual removal?

A. Well, that's clear from this document.

Q. Okay. Okay. Let's move on to the next requirement for this claim.

A. This is actually the final one: The plunger having a vent.

And now watch what happens as the air gets pushed out the sides and out the holes and out through the end.

And so the -- now, this has the front end put back on, because it's being operated -- actuated.

And -- and you can see the vents in operation. So the 3mL Integra does, in fact, have vents. And I think if you look at the next slide, we can take a look at the drawing. This is a Becton Dickinson drawing that was supplied to RTI during this litigation showing what is -- functions as a vent hole in the plunger.

So the animation showed this -- showed the arrow, the blue arrow flowing out through this. Well, that's what it's flowing out through. So there's no question, in my mind, that there's -- there's a vent there.

Q. Now, we looked this morning a little bit quickly at the Murray patent that had a vent in the back, also.

A. Yes, sir.

Q. Is there -- is there a difference between the way that Murray structure is drawn with respect to the retracting piece and the way the BD operates with respect to venting?

A. Well, the Murray one is different in the sense that Murray has -- I mean, it's venting. But the Murray one is there to vent the -- to prevent pressure build-up behind a piston. It's subtle, but it's important.

The vent that Mr. Shaw invented and the vent that's here would serve also, and more importantly, to prevent air from pushing out the front. So -- so you want to lower the pressure at the front end to prevent splatter as described by Mr. Shaw in his patent.

Q. Now, so we have all the -- all the boundary lines checked?

A. Oh, yes. That's the last one.

Q. Okay. And so this is your opinion using those documents and that inspection of the -- of the 3mL Integra.

Does that form the basis of your opinion regarding the infringement question for that product on Claim 10 of this patent?

A. Yes. It forms the basis.

And my conclusion is that the Integra 3mL does infringe Claim 10 of the '077 patent.

Q. Okay.

A. Literally.

Q. Very good.

Now, we have another claim in this patent.
A. Yes, sir.
Q. Claim 25. How does this claim differ generally from Claim 10?
A. In order to infringe this claim, you don't have to have a vent, but you have to have two steps. The plunger has to come to two separate steps unlike a regular syringe.
Q. Okay. And, again, are we going to move through the same general outline?
We're going to show the jurors -- because at the end of the case, they're going to be -- they're going to be asked by this Court whether or not this product falls within the definition of the defined claim.
We're going to move through each of these limitations again?
A. Yes, sir.
Q. And have you got drawings and diagrams to show this to help them?
A. I do. I do as well.
Q. Okay. Let's take a look at the preamble for this claim.
A. The preamble, very brief, a tamper-proof retractable syringe structure designed for one use,

comprising. And there's that word comprising.

So, once again, to infringe this claim, all you have to do is have the one -- things that are listed, regardless of what else you have, whatever bells and whistles, it doesn't matter.

So the first limitation -- this is the preamble and that, of course, is met. So there will be a check there.

So now, here's the first true limitation: A hollow syringe body comprising a syringe barrel having an open back end.

Now, this is much like the previous claim. I'm just showing it in a different way. Here's an assembly drawing from Becton Dickinson showing the front end of the barrel here and the back part of the barrel. And here is that open back end. So this limitation is met.

Q. Okay. And what's --

A. That's the drawing of the 3mL Integra.

Q. What's the Limitation C on your drawing?

A. It simply says that the barrel should have a front-end portion containing a retraction mechanism configured for operation by a plunger.

Now, this is the first time we see a very detailed, color-coded, closeup of the 3ml syringe. So when this -- when we deal with this, I'll try to be thorough, just so to be clear.

Q. So right now, though, all that's required by this claim is a retraction mechanism?

A. Correct. A retraction mechanism of any kind.

Q. Okay. So BD has a special kind, and we're going to talk about it today, but for this -- for purpose of this claim, if it's something -- a mechanism that causes the needle to retract, it would fit the claim?

A. Right. And it needs to be operated by the plunger.

Q. Okay. All right.

A. And that's what you're about to see happening -- well, we were.

Q. Okay.

A. Okay.

Q. Now, it says a plunger reciprocally mounted in sliding sealed contact with the barrel.

A. Okay. This should be familiar. This is the limitation very much like what was in Claim 10, basically that it slides back and forth and functions like a syringe.

So that one is quickly met.

Q. All right. And Limitation E is the plunger having a thumb cap at its back and the -- for working the plunger relative to the barrel and a front end configured to operate the retraction mechanism.

A. Right. Very straightforward. Here's the thumb cap. There's the front end (indicates).

This limitation is met.

Q. The front end has to operate the retraction mechanism in some way?

A. That's correct, the front end.

Q. Okay.

A. Oh, there it was.

Q. All right. And the next limitation is?

A. Okay. E is met.

The next one is the plunger having -- and here's the two-position part -- having a first tactile position -- a tactile first position felt by the user pressing the thumb cap at the end of travel of the plunger in the barrel when the plunger is moved forward to a stop.

And what happens is, as you deliver the medication -- remember this black rubber part here is not allowed to move. It's attached to the plunger. That comes up against this blue part here and the red part here. This is a bridge. This is the needle holder, part of the barrel (indicates).

It comes to a stop. So that's the first stop it comes to. You can feel it. Ah, I'm there. So now that's met by the Integra 3mL.

Q. Okay. And the next requirement in this claim?

A. This one requires that the plunger has a length such that when you are in that position, the back end is still sticking out so you can grab it.

Unlike before when in the end you wanted to be tough so you can't get at it, you want to make sure that when you're in that first position, you can still get at it so the nurse can grab the end and suck the medication up from the vial into the syringe.

Q. So -- so the first position, again, is she can take it all the way down to the stop, and it's still sticking out above the collar?

A. Correct, because the barrel -- the plunger is long enough.

Q. Okay. And then she can grab it and pull it back out and suck medicine up?

A. Correct.

Q. And then where is the second position?

A. The second position happens during the retraction event.

After you deliver the medication, you go past the first stop to the second stop and deliver the medication. And the medication is already delivered -- I'm sorry -- at the first stop. And the second stop goes forward and -- and creates -- the retraction occurs and then the safety aspect in the back occurs.

Q. Okay. Let's see the next requirement of the claim.

A. And we just sort of prespoke about this. You can see the 3ml being activated. You see the retraction mechanism flying back into here. And now you've got this limitation. Here it's slightly different wording. Simultaneously lodging the thumb cap in the open back end, thereby rendering the thumb cap inaccessible -- inaccessible -- I'm sorry -- for grasping.

You can see that you can't grab that with your -- with your thumb and forefinger, your fingers.

Q. Okay. Could you dig it out of there with a fingernail?

A. If you had a good long fingernail, perhaps if you played guitar, or a pen knife.

Q. Okay.

A. Sure, you could pry it out.

The whole -- the whole purpose is that you can't do this (indicates) and have it -- have it come out. It's perfectly safe without having to use extra force to engage some kind of lock.

Q. Okay. Is it your opinion, therefore, that this 3mL Integra infringes, meets all the limitations, and infringes Claim 25 of the '077 patent?

A. Yes. It is my opinion that the 3mL Integra literally infringes every limitation of Claim 25 of the '077 patent and, therefore, infringes.

Q. Okay. Thank you.

Let's move forward.

THE COURT: This is probably a convenient breaking point for our lunch break.

MR. HARDIN: Thank you, Your Honor.

THE COURT: We'll have our lunch recess. Try to be back in time to properly start at 1:30.

We will be in recess.

COURT SECURITY OFFICER: All rise.

(Recess.)

* * * * *

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

/s/______________________ ____________________
SUSAN SIMMONS, CSR Date
Official Court Reporter
State of Texas No.: 267
Expiration Date: 12/31/10

/s/__________________ ________________
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